

Deliverable report for

ENERI

Grant Agreement 710184

Deliverable 6.2.

RE/RI expert set of indicators for e-database

Due date of deliverable: 30.06.19
Actual submission date: 01.07.2019

ENERI identifier	ENERI_deliverable_6.2
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Work Package / Task	WP6 / Task 6.2.
Document Status	Working Document – DRAFT_02
Dissemination level	PU
	* PU – Public; PP – Restricted to other programme participants (including the Commission Services); RE – Restricted to a group specified by the consortium (including the Commission Services); CO – Confidential, only for members of the consortium (including the Commission Services).

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Document History

Version	Date	Reason of change
0.1	27.06.2019	Draft 01
0.2	28.06.2019	Review by Lisa Tambornino (EUREC)
1.0	01.07.2019	final version

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1. Introduction

From the later part of the twentieth century and forward, we have witnessed a significant change in the scientific landscape – for example in terms of an increase in global research and development (R&D) investments, an expansion of global researchers/interdisciplinary research fields and an escalation of scientific advances - together with a change in research infrastructures (i.e. funding structures, performance measures, journals, administration etc.) (Anderson et al. 2013; IAP 2012). In chorus, such progressions and innovations – with their associated risks and challenges - require a corresponding attention to foster responsible conduct of research by promoting professional standards of performing research (i.e. research integrity) and safeguarding moral principles embedded in research (i.e. research ethics) (ENERI 2016; Steneck 2006).

The last decades have shown an increased awareness of matters concerning responsible research and research misconduct, and a great body of practices, procedures, guidelines and legislation have been produced and adopted on a national and international level to enhance ethics and integrity within research. Nonetheless, as shown in the emerging literature within the field, cross-country diversity and heterogeneity still characterise such efforts and continued measures are needed to address and mitigate irresponsible conduct in research (Anderson et al. 2013; Godecharle et al. 2014; Steneck 2006).

Alongside efforts and initiatives to strengthen professional research standards from the part of individuals, research communities/institutions, funding organisations and local governments, among others, transnational expert networks and professional community building constitute another mechanism with the potential to create greater awareness of valuable professional standards and ‘best practices’ across countries, institutions and research disciplines. The ENERI project aims to enhance such cross-country knowledge exchanges by reinforcing existing network structures and establish new knowledge bases for various actors within the fields of research ethics and research integrity with the objective to share and promote information, training activities and capacity building (ENERI 2016). However, one question that arises is how to define expertise and expert competencies within the vast and heterogeneous fields of research ethics and research integrity? Moreover, when building a shared platform/database/e-community for experts, which kind of indicators and criteria should be established for qualified expert membership? This paper aims to answer these questions through the reporting of key empirical project findings and the presentation of a set of expert indicators/criteria constructed on the bases of these findings.

2. Description of Task at the GA

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. Work package 6 addresses the main objective in the project “to create an e-community/database (...) of European and whenever relevant international experts in the different fields of research ethics and integrity”, which “should notably ensure the certification of the knowledge level of the experts.” WP 6 builds on the task in WP 5 which is to set up the actual e-community/database within the existing EU Sinapse database. WP 6 is to explore and construct a set of expert criteria/indicators that can build the foundation for creating a comprehensive, inclusive and international e-database and -community that is able to represent the vast and heterogeneous field of research ethics and research integrity expertise.

3. Objectives and needs of the deliverable

Specified, the main objectives of the task stipulated in work package 6 are:

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(1) to explore and develop indicators that are widely accepted in the heterogeneous field of research ethics and integrity (RE/RI) which represent expertise in the two areas to be implemented in the expert database;

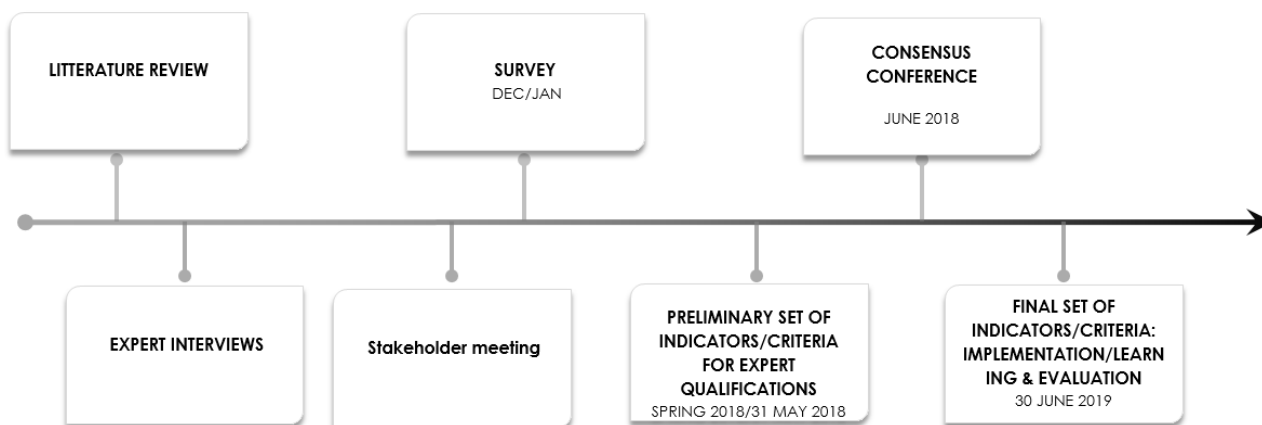
(2) to evaluate the experiences gained by the indicators in regards to validity and usability and to adapt them accordingly; and

(3) to address the construction, mapping, and monitoring of central expert criteria.

A comprehensive empirical program has been created to address the above mentioned issues in a systematic way, although with a particular focus on the construction of RE/RI relevant expert indicators (progress depicted in figure 3.1. below). The first step of the program was directed at the completion of a literature review and desktop research with the objective to review, map and assess existing literature, reports and European projects concerning potential expert qualifications/indicators (see Appendix 1). This review was followed by a qualitative interview study with a number of various RE/RI experts (see Appendix 2). The next phase of the program constituted a quantitative survey that targets a variety of actors, stakeholders and organizations (see Appendix 3). The last part of the empirical programme comprises a series of consensus conferences across four European cities with the aim to include potential data base users and lay people to discuss and validate existing findings on required expert qualifications and certifications for the EU level RE/RI expert database and e-community (see Appendix 4). Taken together, the four studies in the empirical programme

have all informed, substantiated and validated the set of RE/RI expert data base indicators presented in section 5. Individually, they have also contributed to an increased understanding of how RE/RI expertise can be perceived and conceptualized.

Figure 3.1 Overview of WP 6 tasks and data collection



The next sections sum up and report the key findings from the empirical programme that form the basis for the construction of the expert indicators. The full reports and study findings can be found in appendix 1 to 4. Preliminary findings and indicators have also been reported in a previous report¹. Readers already familiar with this previous report can start directly with section 5.

4. Key findings from the empirical programme²

a. Literature review

The literature review (see appendix 1) considers existing material on research integrity and ethics qualifications. The first part of the review concerns a review of EC funded projects focusing on research ethics (RE)/ethic assessment and/or research integrity (RI) (listed

¹ Braun et. al 2018: D. 6.1. Summary of empirical programme and preliminary set of indicators for e-database, pp.1-97.

² The shortened report excerpts has been reproduced from the completed reports included in Appendix 1-4.

below). The second part of the section reviews other types of material, e.g. key EU documents, research findings, institutional reports and EU network material. In this part, the review centres on qualifications related to involvement in Research Ethics Committees (RECs) and Research Integrity Offices (RIOs) and committees.

In general, only a limited amount of resources exist that detail existing and potential expert qualifications related to involvement in research ethics and research integrity. This seems particularly to be the case in the types of RE/RI involvement that extends beyond RECs and RIO's. In terms of the material reviewed for this report, expert qualifications seem more often to be stipulated at a collective level of expertise rather than at the individual level.

While several commissioned studies exist within the fields of RE/RI, only a few - both directly and indirectly - cover the particular issue of expert qualifications. For the objective of this deliverable, three EU projects are considered particularly relevant for further review.

Commission studies for review

Proposal Call	Project Acronym	Project Title	Project Start Date	Project End Date	Sources
FP7-SCIENCE-IN-SOCIETY-2013-1	SATORI	Stakeholders Acting Together On the ethical impact assessment of Research and Innovation	01-01-2014	30-09-2017	http://satoriproject.eu/
RTD-B6-PP-00964-2013	MoRRI	MoRRI – Monitoring the Evolution and Benefits of Responsible Research and Innovation	1-07-2014	1-08-2017	http://www.technopolis-group.com/morri/
H2020-GARRI-2014-1	PRINTEGER	Promoting Integrity as an Integral Dimension of Excellence in Research	01-09-2015	01-09-2018	https://printeger.eu/

Based on the above mentioned projects as well as the literature reviewed, Ethical Assessment Units (EAUs), the basic institutional setup for judging the ethical nature of research, are comprised of different *types* of members therefore each member needs different skills and qualifications. The expectation is that the chairperson has a set of soft skills to swiftly manage process and team, while team members have a mixture of soft and hard skills depending on their position/function within the EAU.

In general, based on the literature and previous EU project deliverables such as SATORI, the most extensive research in RE/RI EAUs to date, **experience in ethics assessment processes is valued over qualification, and training is advised for all members. Specific knowledge/qualification is required for “ethics specialists” and “legal experts”**. A key question in reference to skills and qualifications of EAU members is the validation of such skills and qualifications. While certifications may be one potential form of validation, implementing them into projects is debated. Certifications may be offered to the process/procedure, such as once training has been provided or the person has become a member of the committee. **Regarding certification: procedure and training certification is favored over personal certification**; while there are a number of risks and problems involved in certification, it is assumed that certification in some areas of EAUs (mainly training and process) would improve trust, transparency and credibility.

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b. Expert interviews

The main reasons for conducting expert interviews as a first data collection source are to a) open up the heterogeneous fields of research ethics and research integrity, b) to inductively explore and generate knowledge on potential RE/RI expert criteria from a variety of key representatives and c) to collect contextual information that may complement insights and inform the remaining empirical programme.

Based on the second part of our empirical program (cf. Appendix 2) we have conducted a number of expert interviews³. All expert interviews have been conducted in September and primo October 2017; 11 interviews were performed by phone or skype and the last interview was performed face-to-face. The interviews lasted between 30-60 minutes approximately. The selection of experts/interviewees is based on an ‘information oriented’ selection strategy, with the aims of reaching a broad group of RE/RI experts and achieving variation

³ Experts are defined based on the literature as people with deliberate practice in the field (cf. Ericsson, K. A. 2006. The influence of experience and deliberate practice on the development of superior expert performance. In K. A. Ericsson, N. Charness, P. J. Feltovich, & R. R. Hoffman (Eds.), *The Cambridge handbook of expertise and expert performance* (pp. 683–703). New York: Cambridge University Press)

according to the 'criteria of maximum variation' to then enhance in-depth understandings of potential expert criteria and qualifications. Variation has been pursued according to the following criteria: RI/RE focus; institutional category, geographical location, gender and age.

The institutional category endeavoured to include the following types of representation and experts positioned in:

- National research ethics committees (REC)
- Regional/local research committees (REC)
- European network of RECs (EUREC)
- National research integrity committees/offices (RIO)
- Local/university research integrity committees/offices (RIO)
- European network of research integrity offices (ENRIO)
- National funding organization (involved in ethics review)
- European funding organization (involved in ethics review)
- Government agency (ministry)
- Industrial advisor/consultant on ethics/CSR/corporate sustainability
- Research with expertise within the field of RE
- Research with expertise within the field of RIO

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Interviews have been recorded and subsequently transcribed verbatim by student assistants. All interviews have then been coded thematically in the software programme Nvivo, which allows for a transparent and comparable management and analysis of the empirical data. Interviews have been coded according to a structured coding strategy in alignment with the set of focused codes derived from the key themes explored in the interviews.

Based on these interviews, there is a broad agreement among interviewed experts concerning the value in establishing a database, which is to adopt an inclusive, diverse and transparent approach to RE/RI expertise. Different types of experts highlight different types of experience and competences in accordance with their field of expertise and RE/RI representation. Hence, ethics assessment/review competences are emphasized for ethics research project reviewers, while knowledge of integrity guidelines and codes of conduct are mentioned as important competences for journal editors, for instance. Despite variation, **similarities in core competences and skills appear somewhat consistent across different areas of expertise.** Regarding competences, the following types of acquired knowledge are suggested:

- Ethical competences (deep knowledge of national and international regulation; cases, awareness of moral dilemmas and ethical deliberation)

- Integrity competences (deep knowledge of national and international regulation, policy and guidelines)
- Research/science experience [having performed research activities in the past]
- Legal competences
- Ethics assessment/review experience [having performed ethics assessment in the past]
- Integrity assessment/review experience [having performed integrity assessment in the past]

Experts agree on the importance of a number of skills related to communication, deliberation, collaboration and management. Below, these are summarized and grouped according to hard skills (e.g. education, technical), soft skills (e.g. communicative), process skills (e.g. administrative/management) and emotional skills (commitment, open mindedness).

Hard skills:

- Analytical skills
- Scientific skills
- Ethical commitment/thinking/abilities
- Critical thinking
- Assessment/ review

Process skills:

- Administrative/management
- Turning ideas into recommendations/practice
- Decision-making

Soft skills:

- Communicational
- Interpersonal
- Eye for details
- Ability towards deliberation
- Peace-making, conflict-resolution
- Collaboration

Emotional skills:

- Open-mindedness
- Independence
- Societal/cultural/health care awareness/impact
- Personal commitment

Regardless of RE/RI expertise type, experts interviewed emphasize and prioritize a host of emotional skills as essential for working with and within areas related to research ethics and integrity. Being open-minded towards other perspectives, as well as able to collaborate, for instance, is seen to minimize potential frictions between different discipline practices/guidelines etc. and more broadly between different (normative) perceptions of ethical/integrity standards across research fields, institutions and countries, among others.

Formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria. An optional training course before database entering might be relevant, but a majority of interviewees would not make it mandatory.

Different types of experts are mentioned as potential candidates for the database: experts with an “omnibus” function; local and national RIO’s, researchers in RE/RI; medical researchers; REC members; editors; publishers; individuals with national/EU project evaluation/review experience; RE/RI university teachers; research funders; RE/RI communication trained individuals; specialists in constitutional law/applied ethics/philosophy/social science/psychology/economy/criminology; practitioner network members (e.g. ENRIO); RE/RI policy experts. A few interviewees furthermore mention that lay people might be relevant to include in the database similar to the composition of REC’s.

An optional training course before database entering might be relevant, but a majority of interviewees would not make it mandatory. Several also question how to design a standardised course that would work as a common expert foundation.

A few experts see a personal issued database certification as a good idea. Several view it as acceptable, but find it difficult to see its real value and the incentives for issuing one.

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As an extension to our expert interviews we have included a workshop for experts on our expert stakeholder meeting in Athens to discuss these topics further⁴. On the issue of certification, stakeholders reached consensus and agreed to the advantages of issuing a personal certification for expert database membership. Expert interviewees, in turn, were much more divided in their view on the benefits of certification.

As for operationalization the inclusion of soft skills into the database of a peer-reviewed system was suggested in which, similarly to LinkedIn, other members of the database could add soft skills to any member of the database and support with evidence as to where and how this soft skill was demonstrated.

⁴ A stakeholder conference took place in Athens, September 2017 and brought together 55 different stakeholders from universities, industry, science journalism, ministries as well as project participants from several European projects on research ethics and research integrity. The conference aimed to bring together expertise from various fields and perspectives to discuss central questions as to the current and future state of RE/RI in terms of practices, infrastructures, committee compositions, among other related subjects. The conference also included a workshop on “what constitutes expertise and qualifications in RE/RI?”

c. Quantitative expert survey⁵

A questionnaire was created in January 2018 and was distributed by the European Network of Research Integrity Offices (ENRIO) network as well as was shared at the EUREC members meeting that took place on 15th of February 2018 in Berlin. The target sample was 100 respondents and after intensive communication and repeated reminders, 125 respondents filled out the questionnaire. In selecting respondents we used non-probability sampling as randomization was not possible in order to obtain a representative sample. Following up on the expert interviews and utilizing the core expert networks of RE/RI, ENRIO and EUREC, we used expert sampling as a subset of non-probability sampling.

We contacted and utilized the membership of two main RE/RI organizations with a broad expert base and good geographic distribution:

- European network of RECs (EUREC)
- European network of research integrity offices (ENRIO)

Respondents find an international database/e-community to be a very useful initiative and name various uses from the potential use to ‘find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. and ‘find research ethics experts for European/international networks’. **Based on the survey we may conclude that respondents value ‘experience’ or praxis in RE/RI assessment the most;** while they also would like to see database member experts possess some theoretical ethics/philosophy (and to a lesser extent ‘legal’) knowledge to back up their practical experiences.

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When assessing required skills, respondents say that **experts should be personally committed, open-minded and impartial people, with analytical minds to solve the ethical/moral dilemmas that may arise as problems.** Simultaneously, they should also be able to convey and deliberate their potentially diverging opinions or point of views. Respondents suggest that the design of the database should (pre)define all skills and expertise of the database members, as well as years of practical experience, as somewhat more important than specific educational background. When it comes to specific skills and competences, **respondents primarily value RE/RI experience as well as previous experience in RE/RI commissions, closely followed by scientific/research experience.** As for the structure of the database, respondents value a selection of short self-descriptions based on key areas of expertise, rather than tick-off standardized categories or a few standardized themes and blank cells to be filled in with whatever the expert finds important.

⁵ ENERI Project 6.1. Subtask 1: Braun et al. (2017). RI/RE expert qualifications, Appendix 2 Results from a quantitative survey

As for registration of experts in the database respondents seem to be split between an open and a controlled approach to registration; while a relative majority would opt for a more controlled approach (39%). The biggest number of respondents would suggest an EU controlled registration (25%), while some respondents suggest that experts should be nominated by the relevant national bodies (14%). Open access and self-assessment is a clearly minority opinion (12%).

The majority of respondents claim that training should only be offered on a voluntary basis and not be made mandatory and that 'any ethics/integrity training' should be accepted as opposed to a certified training by an official body. When defining the type of certification required for the training, a majority would opt for a certification to be received following completion of the course as opposed to requiring certification of the teaching method of the specific course.

Respondents are split as to whether some kind of personal certification be issued for members of the database with a somewhat higher proportion of respondents opting for no personal certification (35%) over issuing some form of certification (26%). This is consistent with the respondents position on whether such a certification would be an incentive to enter the database (33%) as opposed to those who think that such certification would not provide any incentive (33%).

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The findings from the expert interviews and expert survey led to a number of questions and a set of preliminary indicators that were tested, discussed and fine-tuned in the series of consensus conferences.

Preliminary indicators (see appendix 4)

Database as a whole:

- Both interview experts and experts in the quantitative survey find an international database/e-community to be a very useful initiative and name various uses from the potential to 'find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. and to 'find research ethics experts for European/international networks'.
- There is a broad agreement among experts to adopt an inclusive, diverse and transparent approach to RE/RI expertise.

Database design:

- Database should

- (pre)define all skills and expertise of the database members (but some level of co-design is accepted);
- Contain short self-descriptions (focusing on evidence based experience) on key areas of expertise rather than tick-off standardized categories.

Database registration:

- It is advised to use a controlled (supervised and managed) approach either by an EU institution controlled registration or nomination of experts by relevant national bodies (as opposed to an open registration process based on self-registration).

Database indicator(s):

DI1: Inclusivity

DI2: Diversity

DI3: Transparency

DDI1: Definition of skills and expertise

DDI2: Description of experience

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Skills and qualifications:

- Experience in ethics assessment processes (as expressed in number of years; membership in EAUs; etc.) is valued generally by experts over qualification;
- From a qualifications point of view experts are to possess:
 - Theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences;
 - Experience in
 - Scientific/research skills
 - Ethical commitment and awareness
 - Critical thinking
 - Assessment and review
 - Experience in
 - Interpersonal communication/debate

Expertise indicator(s):

EI1: Quantifiable experience in EAUs or assesement processes

EI2: Ethics/Philosophy knowledge

EI3: Specific and relevant experience in scientific research

EI4: Peer offered experience in critical thinking, ethical commitment

Training:

- Training should be offered on a voluntary basis (especially for those with limited or no EAU experience)
- 'Any accredited ethics/integrity training' (without having defined who would provide such accreditation) should be accepted as opposed to a certified training by an official body.

Training indicator(s):

TI1: Training option (mandatory/volunteer)

TI2: Provider of training

Certification:

- Potential for
 - personal certification for expert database membership
 - personal certification for participation in training course offered

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Certification indicator(s):

CI1: Certification of database membership

CI2: Certification of training participation

d. Series of consensus conferences

The consensus conferences took part in four European cities (Aarhus, Athens, Vienna and Vilnius) during the month of June, 2018. Local ENERI teams assisted in the preparation (venue, invitations, catering) and stakeholder selection.

The consensus conference format applied attempts to reach a middle ground between 'lay persons' and 'expert participation' consensus conferences and invited a varied group of people who are not experts in RE/RI but are/may be stakeholders relevant to RE/RI processes. The goal was to reach consensus among invited stakeholders in required qualifications and certifications for EU level RE/RI expert database.

12-15 stakeholders in each venue were selected from the following potential future database “user” groups:

- People with RE/RI committee experience
- University management
- Funding agency
- Researchers
- Students
- Industry people
- Science journalist
- Lawyer/legal expert
- Government/local/national

Altogether 50 stakeholders participated in the four cities.

In each of the consensus conferences, six questions were posed focusing on:

- Structure and particular design of individual expert profiles;
- Format of registration of experts;
- Formal and relevant education, RE/RI experience;
- Optional training course;
- Personal certification

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Specifically, the six questions discussed in each consensus conference are the following:

- Q1: Should a broad, diverse and inclusive or a predetermined, limited approach (defined by an authoritative entity, including the ENERI project) to RE/RI expertise be applied? (expert types, RE/RI topics, organizational levels etc.)
- Q2: Should individual profiles be highly structured and include a large number of ‘tick-off’ standardized categories or should they be semi-structured; include predefined key areas/themes of expertise to be filled in with short descriptions + open categories?
- Q3: Should the database offer self-registration or should members be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental and institutional bodies?
- Q4: Should members go through a training course before being allowed to register in the database?

- Q5: Should individual profiles focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAUs participated in) within particular areas of expertise or experience need not be quantified?
- Q6: Should the database require personal certification of any type or is such certification not required?

The consensus conferences mainly supported the view of the experts. Potential users and other key stakeholders come to a conclusion (with strong minority opinions in the case of Aarhus regarding Q1 and Q3) that:

- Q1: A broad, diverse and inclusive approach should be applied to RE/RI expertise;
- Q2: Individual profiles should be semi-structured; they are to include predefined key areas/themes of expertise to be filled in with short descriptions + open categories;
- Q3: The database should offer self-registration of experts;
- Q4: Members must not go through a training course before being allowed to register in the database, but such course(s) should be offered as optional;
- Q5: Individual profiles should not focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAUs participated in) within particular areas of expertise (majority position only);
- Q6: The database should not require personal certification of any type to enter the database.

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In a few cases there was a strong divergence from the majority position [Q1; Q3: Aarhus] and in case of Q5 opinions were diverging and no consensus among the four locations can be established. In all consensus meetings, strong and useful remarks were added to the main consensus that may be used well when designing the database.

Based on the CCs potential users and other key stakeholders, a broad, diverse and inclusive approach to database membership is suggested. As for database structure, participants recommend a semi-structured approach comprising of predefined key areas of expertise to be filled in with short descriptions, complemented with open categories to add specific skills and experience. Participants of the CCs opted for self-registration of experts (with some potential minimum experience requirements). They also suggest that the platform should offer optional training course(s) in ethics as well as other skills. Participants suggest that experience should not be quantified e.g. by the number of years, cases dealt with etc., however a strong minority opinion emerged that some quality measures should also be applied to

inform users about the specifics of the experience that has been quantified. It emerged that personal certification should not be applied as an entry criteria.

5. RE/RI final set of expert indicators

The final set of indicators presented below refines and deepens the preliminary set of indicators (see section 4.c and appendix 5 for a provisional database operational indicator description) in alignment with the entire set of empirical findings, the existing data base set up and expert descriptors available through Sinapse. Sinapse is a web communication platform that aims to promote expertise in policy making and governance at the EU level. Currently, Sinapse involves 35.398 members and 1619 organisations (europa.eu/sinapse). Within the Sinapse database, specific “e-communities” can be established that “enable groups of members and organisations with a common interest to share and exchange information in a dedicated environment which can be graphically personalised and linked to the initiator website” (europa.eu/sinapse). The ENERI project has built an E-community entitled “European Network of Research Ethics and Research Integrity”. Presently, 154 members have joined this RE/RI dedicated E-community. Per default, all members answer categories stipulating nationality, gender, working language, organisational affiliation, type of organisation and type of activity (e.g. research funding, scientific advice etc.).

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In alignment with the empirical based findings on relevant RE/RI expertise as well as key database user needs, the following set of indicators specify criteria related to 1) data base structure and organisation 2) expertise affiliation, experience and skills 3) Training requirements and options 4) certification prerequisites.

Database indicator(s):

DI1: Inclusivity

- ✓ Experts should be inclusive of all types and experiences in RE/RI and related fields.

DI2: Diversity

- ✓ Experts should be diverse (specific attention to be paid to gender and geographical distribution)

DI3: Transparency

- ✓ Data should be proper and up-to-date
- ✓ Data should primarily be pre-defined
- ✓ Open-categories should be self-explanatory
- ✓ Documents should be up-loadable
- ✓ Motivation for entering into the database should be described (max 200 words)

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DDI1: Definition of skills and expertise

- ✓ Skills should be tick-boxed and briefly explained

DDI2: Description of experience

- ✓ Experience should be non-quantified (e.g. number of years or number of cases options; but short quality descriptions if appropriate) → short 200 words synthetic description of key experiences/activities within the RE/RI fields
- ✓ Peer endorsement; evaluation; reflection options provided (star rating, one word rating). Peer categories such as shared experience (e.g. membership in EAU), peer endorsement of skills (e.g. soft skills)

Expertise indicator(s):

EI1: Institutional RE/RI affiliation

✓ Type of expert affiliation:

- Research performing organization (RPO), expertise in research ethics
- Research performing organization (RPO), expertise in ethics in general
- Research performing organization (RPO), expertise in research integrity
- National research funding organization (RFO), expertise in ethics review
- National research funding organization (RFO) expertise in research integrity advise/policy
- European funding organization (expertise in ethics review)
- European funding organization (expertise in research integrity advise/policy)
- National research ethics committees (REC)
- Regional/local research committees (REC)
- National research integrity committees/offices (RIO)
- Local/university research integrity committees/offices (RIO)
- European network of research ethics committees
- European network of research integrity offices
- Government agency, expertise in research ethics
- Government agency, expertise in research integrity
- Industrial advisor/consultant on ethics/CSR/corporate sustainability
- Journal editor, expertise in research ethics
- Journal editor, expertise in research integrity
- Media, expertise in research ethics
- Media, expertise in research integrity
- Other, please specify:

EI2: Specific and relevant experience in scientific research

- ✓ Quantified research experience
- ✓ Level of expertise (low, medium, high)

EI3: Ethics/Philosophy/Law knowledge

- ✓ Formal tertiary education in philosophy, ethics or law → if yes, description of level of degree, institution and title
- ✓ Formal non-academic training in philosophy, ethics or law
- ✓ In case of legal training: specific field e.g. data management, human subjects etc.

EI4: Experience in EAUs or assessment processes

- ✓ Types of experience:

- Assessment
- Evaluation
- Proposal writing (ethics)
- Expert opinion
- Teaching and training provision
- Specific experience in field:

- RE
- RI

- Specific experience in ethical field

- Medical
- Digital/ICT
- Gender
- Other

EI5: Ethics assessment/review experiences

✓ Types of specific subject areas of experience:

- Open specification

✓ Types of representation:

- Chairperson
- Secretary
- Field practitioner
- Ethics specialist
- Discipline expert
- Legal expert
- Institutional representative
- Public representative
- Other

El6: Integrity assessment/review experiences

✓ Types of specific subject areas of experience:

- Open specification

✓ Types of representation:

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- Chairperson, institutional level
- Chairperson, national level
- Member of national Research integrity committee
- Substitute member of national research integrity committee
- Secretary
- Research integrity advisor (RIA)
- Integrity specialist
- Discipline expert
- Legal expert
- IT expert
- Public representative
- Other

EI7: Ethical competencies

✓ Types of competencies:

- Ethical appraisal/review/assessment
- Research
- Evaluation
- Policy guidance
- Proposal writing
- Expert opinion
- Teaching
- Dissemination
- Other

✓ Short self-description

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E18: Integrity competencies

✓ Types of competencies:

- Integrity appraisal/review/assessment
- Research
- Evaluation
- Policy guidance
- Proposal writing
- Expert opinion
- Teaching
- Dissemination
- Other

✓ Short self-description

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E19: Legal competencies

✓ Types of competencies:

- Integrity appraisal/review/assessment
- Research
- Evaluation
- Policy guidance
- Proposal writing
- Expert opinion
- Teaching
- Dissemination
- Other

✓ Short self-description

EI10: Collaboration skills (indication of the three most important skills and skills that the expert possesses)

✓ Type of skills

- Ability towards deliberation
- Open-mindedness
- Independence
- Communicational
- Interpersonal
- Ability towards deliberation
- Peace-making, conflict resolution
- Personal commitment

EI10: Process skills (indication of the three most important skills and skills that the expert possesses)

✓ Type of skills

- Administrative/management
- Turning ideas into recommendations
- Decision-making
- Eye for details
- Critical thinking
- Ethical commitment and awareness
- Societal/cultural/health care awareness/impact

Training indicators:

TI1: Training option (voluntary)

✓ Trainings completed

- Training course by ENRIO, specification
- Training course in Ethics, specification
- Training course in Integrity, specification

✓ Trainings offered (pointers)

✓ Trainings suggested (links)

Certification indicators:

CI1: Certification of database membership


✓ No certification as entry criteria


CI2: No certification of (training or database) participation

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Within the current Sinapse structure, the majority of expert criteria (i.e. RI/RE affiliation, experience and skills as included above) have been implemented directly into the standard expert profile (see excerpt in figure 5.1. below). Peer endorsement is not an option within the current system, and experts are instead only to assess themselves in terms of collaboration and process skills. Training indicators are currently included as criteria for completed training sessions and not as training offered/training suggested. Certification (database and training) has not yet been applied in the initial e-community formation, but will be settled in the future use of the database.


Figure 5.1. Database excerpt of RE/RI indicators


Getting Started  Server Not Found


ethics or law 


☐ Level of expertise

☐ Affiliation with RE/RE institutions 

☐ Affiliation with RE/RE institutions (other) 

☐ Have you completed a training course offered by ENRIO ? 

☐ Did you complete a training course in research ethics ? 

☐ Did you complete a training course in research integrity ? 

☐ Please select key research ethics competencies


☐ Please describe key research ethics competencies (other)


☐ Please select key research integrity competencies:


☐ Please describe key research integrity competencies (other)


☐ Please select key legal competencies


☐ Please describe key legal competencies (other)

☐ Experience with ethics assessment/review type of representation 


☐ Experience with ethics assessment/review 

☐ Experience with integrity assessment/review 

☐ Experience with integrity assessment/review type of representation 

☐ Collaboration skills 

Ability towards deliberation
Open-mindedness
Independence
Communicational
Interpersonal
Ability towards deliberation

Multiple choices are possible. 

6. Provisional evaluation and learning insights

In order to set up the ENERI e-community database (as part of ENERI WP 5), the 154 existing expert members have been personally invited by members of the project and qua their expert competencies, experiences and collaborations within the field of research ethics and research integrity. Members have been invited to join the database (with the general Sinapse set of existing expert criteria) prior to the data base launching of the final set of RE/RI expert indicators/descriptors. This implies that members were invited to extend their expert profiles after their initial registration into the database. At present, only 12 of the expert members have extended their profiles in accordance with the specific set of RE/RI expert criteria.

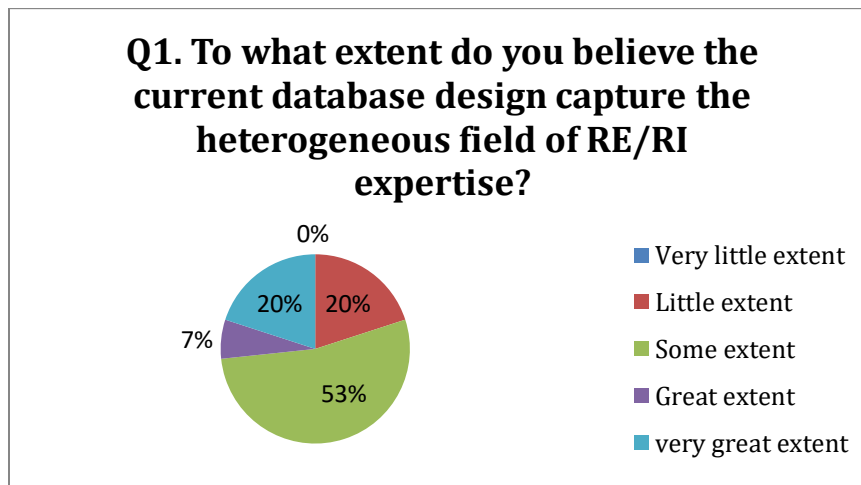
All members have received a kind reminder to complete their expert profiles and, likewise, to answer a short questionnaire regarding their perceptions of the database design. This small online survey was distributed to members primo June and a reminder was send out shortly afterwards. The questionnaire includes the following five evaluative questions (see appendix 6):

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- 1) To what extent do you believe the current database design capture the heterogeneous field of RE/RI expertise? (five-level Likert item from very little extent to very great extent)
Optional: please feel free to elaborate on the question (text box)
- 2) To what extent do you believe the current database design captures the appropriate information to assess RE/RI expertise? (five-level Likert item from very little extent to very great extent)
- 3) Do you think that the information provided is useful for potential users in need of RE/RI expertise? (five-level Likert item from very little extent to very great extent)
Optional: please let us know what is to be added/deleted from the database information (text box)
- 4) Do you believe one or more of the existing criteria/descriptors should be further specified? (yes/no, if yes, please specify)
- 5) Do you believe one or more additional expert criteria should be added to the database? (yes/no, if yes, please specify)

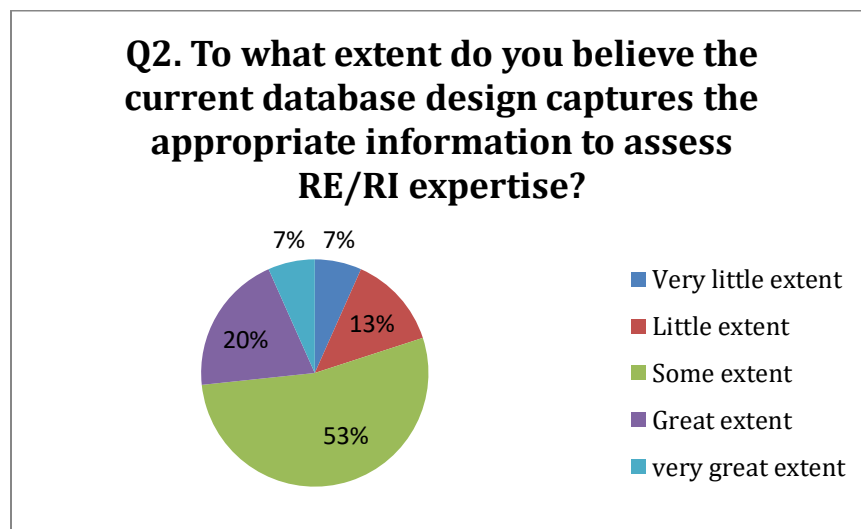
- 6) If you have any recommendations on how to improve the expert database, please state them below (text box)

Due to our reporting time frame and a relatively small sample of respondents, only provisional user evaluation and learning insights can be included. While we presume that the sample includes the entire population (12 out of the 12 experts with extended profiles), the evaluation would benefit from a greater representation of the entire database (see recommendations below). Hence, the following assessment is based on 12 completed questionnaires from existing members:

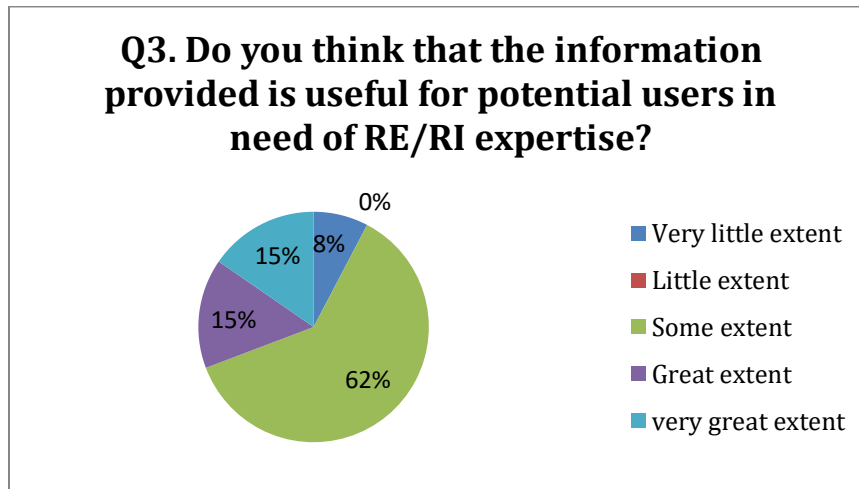


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The overwhelming majority of respondents agree that the current database design does capture the heterogeneous field of RI/RE expertise (80%), with 20% claiming that it does capture it to a very great extent.

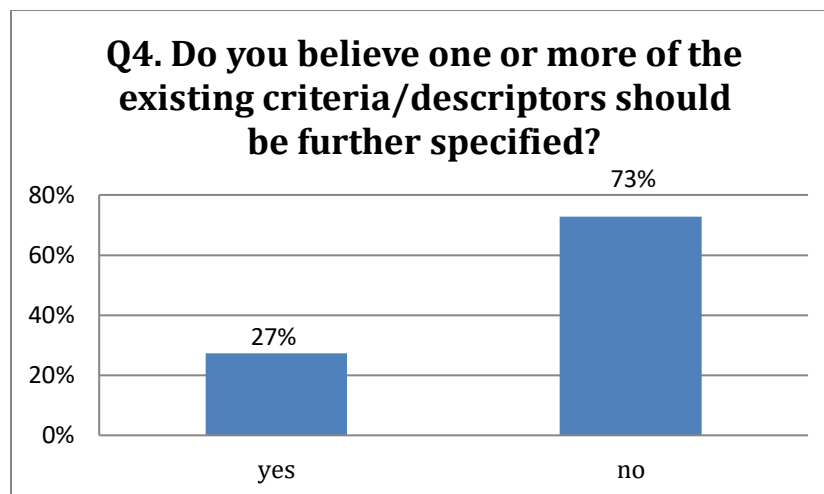


Similarly, the overwhelming majority of respondents agree that the current database design captures the appropriate information to access RI/RE expertise (80%), with 20% claiming that it does capture it to a great extent and a further 7% claiming that it does capture it to a very great extent.



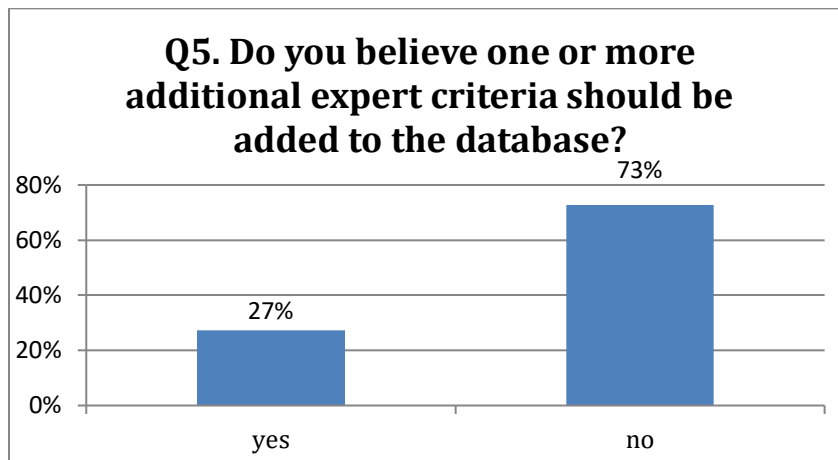
The next question concerned the usefulness of the information in the database from a user's point of view. Respondents agreed that the information provided is useful (92%) with one third of the respondents claiming that it very useful for potential users.

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In accordance with the previous findings, a majority of respondents do not propose further information or additional specifications to the criteria/descriptors offered in the database (73%). In cross analysis with the previous question it is clear that while 62% percent claim

that the descriptors provided are useful to some extent only, the majority agree (73%) that these are the best criteria we have to date to inform potential users.



In accordance with previous findings respondents do not see any other relevant information or criteria missing from the database descriptors.

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Summary:

This confirms the overall finding of the survey that those experts who have filled in the new descriptors (a) are content with the findings of our research altogether and approve of the descriptors to capture the field of RI/RE; (b) also agree that the descriptors express expertise in RE/RI in an appropriate and user-friendly way. To confirm the previous findings (c) more than two-third of these respondents also do not see any potential descriptor missing from the database or a need for further specification of the descriptors at this point.

Some respondents also suggested in the open part of the questionnaire that (a) in some of the categories multiple selection options may be allowed, and (b) keep up the ability of feedback and later review. These suggestions may be taken up at a later review stage.

7. Recommendations for next steps

Due to the time limits surrounding the execution of the project (i.e. project termination, WP deadlines and data base launching), the RE and RI e-community is still in a formative phase of establishing its member base with the associated RE/RI extended profile features. In view of this, we recommend the following future actions to be considered in the ongoing development of the e-community construction:

- Existing members should be encouraged to complete their profiles to maximize the potential of the e-community to be a shared platform for knowledge exchange and a useful source for identifying required RE/RI expertise
- The question of certification should be settled as to whether it should be issued at all or whether it should be issued as a training certificate (for database related RE/RI training) and/or issued as a personal certificate for database expert membership
- Database registration of members should be decided as to whether it should a) offer self-registration b) be managed by an EU institution with or without the combination of a nomination process of experts by relevant national bodies
- The responsibility of data base maintenance (i.e. registration, feature upgrading etc.)
- Continual launches of small and precise evaluation schemes could add to a continued effective database aligned to main user needs. This would be in agreement with the suggestion received in the small review questionnaire. It would also provide a more valid and representative understanding of the user needs of the collective e-community when all or a great majority of experts have completed the extended RE/RI profile.

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Appendix 1. Literature Review

RI/RE expert qualifications

Results from the literature review

ENERI, WP6, 6.1
2017

Tine Ravn, Robert Braun & Laura Drivdal

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1. Introduction – Ethics and integrity in research

Since the latter part of the twentieth century, developments within science and technology have progressed apace: global R&D investments in research have enlarged significantly; the number of researchers worldwide has increased by millions within the last decades and scholars are increasingly working within international and interdisciplinary research fields (IAP 2012). Moreover, scientific advances related to emerging technologies, for instance within the field of biotechnology, have brought forth significant and substantial improvements but, in chorus, they have also raised new risks and ethical questions concerning the implications for the human and non-human subjects involved (ENERI 2016).

‘Innovation in natural knowledge and in its technological applications demands a corresponding capacity for social innovation’ (Jasanoff 2004, 91). The quotation refers to the science-society co-productive nature of scientific knowledge and a corresponding obligation for inclusive and democratic governance. However, one could equally argue that both technological and social innovations demand amplified attention to both research ethics (i.e. moral principles embedded in research) and research integrity (i.e. professional standards of conducting research) or, taken together, efforts to foster responsible conduct of research (RCR) (Steneck 2006). As Pickersgill argues ‘science today is an “ethical” business’ (2012, 579) and ethical governance in relation to regulation, funding and distinct research practices constitute a growing concern in national and transnational contexts.

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The issue of RE/RI has always been immersed in research processes. Nonetheless, the changing nature of science (j.f. above) and of research infrastructures (i.e. funding structures, performance measures, journals, administration etc.) together with a rising number of cases of research misconduct, have resulted in a steady increase in the production of knowledge within this field. Researchers show a growing interest to understand the causes and effects of research misconduct and questionable research practices (QRP) and to conceptualise and clarify the diverse terminology related to responsible conducts of research (Anderson et al. 2013; Godecharle et al. 2014; Steneck 2006). Even so, such efforts have primarily pertained to the biomedical and behavioural sciences (Steneck 2006) and great diversity still exists in knowledge on performing responsible research across scientific fields. Similarly, while efforts to promote responsible research have resulted in global statements such as the ‘Singapore Statement of Research Integrity’⁶, a production of codes of conducts and a variety

⁶ www.singaporestatement.org/statement.html

of international and national bodies to assess, oversee and reinforce responsible research practices, cross-country heterogeneity still characterise the practices, legislation, guidelines and procedures of enhancing ethics and integrity within research. Such heterogeneity also portrays efforts to handle and manage allegations of irresponsible research, however no transnational 'harmonised procedures' exist (ENERI 2016; Godecharle 2014).

A key declaration in the Singapore Statements reads that 'the value and benefits of research are vitally dependent on the integrity of research'⁷ Conversely, the impact of irresponsible research conduct may be detrimental to the 'financial, political, and social support for science' (Anderson 2013, 217). Specified, adverse effects may influence research in the following four ways 1) undermine the reliability and trust in the 'research record' 2) impair the mutual trust between researchers and between researchers and the public 3) squander and misuse funds for research and 4) result in decision-making that may cause harm to individuals (researchers themselves and lay publics) (Steneck 2006; 61). Despite growing efforts to understand and document the extent of research misconduct and QRPs - of which the latter may deem worse due to its much greater prevalence (Fanelli 2009; John et al. 2012) - the nature and frequency of irresponsible research conduct is not well established (Fanelli 2009; Steneck 2006).

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Several mechanisms, standards and actions are already implemented to further substantiate and foster research ethics and integrity, but as documented in the emerging literature within this field, further measures are required to address and mitigate irresponsible conduct in research (Anderson 2013; Steneck 2006). As a starting point, irresponsible conduct in research need to be addressed in terms of 'professional standards, not professional ideals' (Steneck 2006, 67) and, hence, as embedded norms integrated in scientific practices and not as mere ambition. In addition to individual, institutional and national measures to safeguard and stimulate such professional standards, transnational efforts to increase and harmonise standards are seen to benefit from professional community and network building and from knowledge exchange and the formation of knowledge bases, among other mechanisms. One way to promote such exchanges is through the setting-up of expert groups and networks whose expertise and qualified membership may add to greater awareness, dissemination, substantiation and harmonisation of cross-country knowledge, standards and 'best practices' within the fields of research ethics and research integrity.

⁷ preamble, www.singaporestatement.org/statement.html

The following report constitutes a small-scale background study with the aim of identifying, reviewing and mapping potential expert qualifications/indicators. In particular, the review serves as a first step in the process ‘to create an e-community/database (...) of European and whenever relevant international experts in the different fields of research ethics and integrity’ (ENERI 2016, 16). Hence, the review primarily addresses the identification of central, significant and acknowledged expert qualifications and seeks to answer the following two questions:

- Based on key texts, articles and project findings, which expert indicators/criteria for involvement in RE/RI can be identified?
- What are the main forums, formats and mechanisms for incorporating and promoting ethical and integrity related concerns in research?

Due to the objective of identifying particular expert qualifications (rather than a review of the RI/RE field in general), the review will have the character of a synthesised review. The review will furthermore approach research ethics and research integrity in a collective manner as part of the definition of responsible conduct of research (RCR). Particular definitions and terminology applied will be specified in the section below.

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2. Defining the fields of research ethics and research integrity

Complete consistency in terminology and definitions within the field of RE/RI does not exist in the pertaining literature. Nonetheless, the growing body of work within these fields and, consequently, the work performed to understand and conceptualize (ir-)responsible conduct of research increasingly seem to add to a more collective and coherent nomenclature. While research ethics and research integrity often are treated as distinct research fields, they also ‘combine general ethical reflections, ethics and law as academic disciplines addressing research activities, moral attitudes of researchers, normative policies of stakeholders [...] and various ethical expectations of civil society’ (ENERI 2016, 3). In this review, we adopt the concept of responsible conduct of research (RCR) as an overall framework that encompasses both the notion of research ethics and research integrity. A definition of RCR covers:

‘Conducting research in ways that fulfill the professional responsibilities of researchers, as defined by their professional organizations, the institutions for which they work and, when relevant, the government and public’ (Steneck 2006, 55).

Within this terminology, research integrity is defined as ‘research behaviour viewed from the perspective of professional standards’ and research ethics as ‘research behaviour viewed from the perspective of moral principles’ (Steneck 2006, 56). Research integrity comes from the Latin word *integer* and refers to the aspect of wholeness or completeness and, as encompassed within the Singapore statement, relate to the ‘trustworthiness of research’. Integrity refers to research findings and the process in which they are produced (i.e. data, methods, interpretation and presentation/reporting) and whether such processes and findings meet established and appropriate scientific, legal and professional standards. By comparison, ‘research ethics’ pertains to the moral issues that occur in the research design and its implementation, for instance in relation to the protection of humans, animals, environment, data as well as the proper protection of other objects (Anderson et al. 2013; ENERI 2016; Steneck 2006; Strand et. al 2015).

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Responsible conduct of research represents ideal research behavior on the part of individuals and institutions. Opposite, scientific misconduct constitutes the worst kind of research behavior and, despite definitional variation, it covers the common understanding of incorporating fabrication (data/case invention), falsification (data/results/process/equipment manipulation), and plagiarism (copying of ideas/data/results/words without crediting), (FFP) (Anderson 2013; Fanelli 2009; Steneck 2006). While ideal research behavior and scientific misconduct characterize opposites, questionable research practices (QRP) fall somewhere in between as depicted in figure 1 below. Such misbehaviors constitute a range of different practices and may represent a ‘grey area’ of research conduct that is difficult to determine, and often considered less serious than FFP practices.

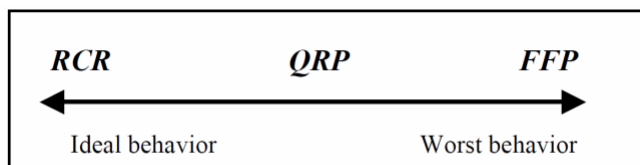


Fig. 1. Current framework for Defining Research Behaviors

(Source: Steneck 2006, 54)

Likewise, QRP are more difficult to define/conceptualize and a broad terminology is often employed. QRP may for instance be defined as ‘design, analytic, or reporting practices that have been *questioned* because of the potential for the practice to be employed with the purpose of presenting biased evidence in favor of an assertion’ (Banks et al. 2016, 7). Examples of QRPs include selective publishing of results/hypotheses reporting; harking (‘hypothesizing after results are known’); ‘round-off’ p-values; hide conflicts of interests; breach of confidence, among other actions (Banks et al. 2016, 8; Fanelli 2009; IAP 2012). In all instances of misconduct, the aspect of intentional deception is pivotal. Contrary, unintentional errors and interpretative/design variation are not viewed as instances of scientific misconduct (Fanelli 2009).

Responses to allegations of irresponsible research behavior differ from country to country; in some countries, national funding agencies such as the German DGF Ombudsman may act as an alternative reporting/mediator mechanism. In other countries, national bodies may function as advisory bodies only or have institutional oversight or sanctioning responsibilities. Nonetheless, in most countries the concerned university or research institution has the main responsibility for handling allegations of scientific misconduct and QRP (IAP 2012, 4).

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3. Review of empirical research on RI/RE qualifications

3.1 Introduction

The following section reviews existing material on research integrity and ethics qualifications. The first part of the section concerns a review of EC funded projects focusing on research ethics/ethic assessment and/or research integrity. The second part of the section reviews other types of material, e.g. key EU documents, research findings, institutional reports and EU network material. In this section, the review centres on qualifications related to involvement in Research Ethics Committees (RECs) and Research Integrity Offices (RIOs) and committees.

3.2 Commission studies and projects on RI/RE

While several commissioned studies exist within the fields of RE/RI, only a few - both directly and indirectly - cover the particular issue of expert qualifications. For the objective of this report, three EU projects are considered particularly relevant for further review (see table 3.2.1 below). Among these projects, the SATORI project details most specifically with expert qualifications concerning ethics committee members.

Table 3.2.1 Commission studies for review

Proposal Call	Project Acronym	Project Title	Project Start Date	Project End Date	Sources
FP7-SCIENCE-IN-SOCIETY-2013-1	SATORI	Stakeholders Acting Together On the ethical impact assessment of Research and Innovation	01-01-2014	30-09-2017	http://satoriproject.eu/
RTD-B6-PP-00964-2013	MoRRI	MoRRI – Monitoring the Evolution and Benefits of Responsible Research and Innovation	1-07-2014	1-08-2017	http://www.technopolis-group.com/morri/
H2020-GARRI-2014-1	PRINTEGER	Promoting Integrity as an Integral Dimension of Excellence in Research	01-09-2015	01-09-2018	https://printeger.eu/

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SATORI - Stakeholders Acting Together On the Ethical Impact Assessment of Research and Innovation

SATORI is a 45-month long project, comprising of 17 partners from 12 countries, including an intergovernmental organisation. The aim of it is to improve respect for ethics principles and laws in research and innovation, and to make sure that they are adequately adapted to the evolution of technologies and societal concerns. The partners will develop an ethics assessment framework based on thorough analysis, commonly accepted ethical principles,

participatory processes and engagement with stakeholders, including the public, in Europe and beyond.

Documents reviewed:

- D.4.1. A reasoned proposal for shared approaches to ethics assessment in the European context
- D.7.2. Exploring the potential of conformity assessment techniques to support ethics assessment
- CWA (CEN Workshop Agreement), “Ethics Assessment for Research and Innovation – Part 1: Ethics Committee”.

Expertise as input for indicators/qualifications

The table collects the main aspects of needed *expertise* as observed/detailed in SATORI deliverables and the CWA (which is the basis for the standard of setting up and operating Ethics Committees on all levels of research ethics assessments).

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Table 3.2.2. Examples of indicators/qualifications retrieved from SATORI

Potential indicator/qualification	RI/RE related	Type of expertise (E.g. educational, teaching, network etc.)	Organisational level of expertise (E.g. institutional, national, regional etc.)	Relevant scientific discipline (yes/no/specify)	Specific representation (E.g. type of stakeholder, ex. ministry, editor etc.)
		Scientific Ethical; Administrative Research	Institutional Administrative	Yes: any scientific or technical area relevant	End user Layperson

Skills of EAU (Ethics Assessment Unit [Ethics Committee]) members

The table collects the main aspects of needed *skills* as observed/detailed in SATORI deliverables and the CWA (which is the basis for the standard of setting up and operating Ethics Committees on all levels of research ethics assessments).

Table 3.2.3. Skills of EAU

Stakeholders/members	Chairperson	Secretary	Field Practitioners	Ethics Specialists	Experts from various disciplines	Institutional Representatives	Legal experts	Public representatives
Hard skills	- technically, ethically and administratively professional - appropriate education; training and experience							
			Scientific/ technological	Ethics Religious traditions	Scientific/ technological	Competency in representing the institution	Legal	End user competency
Soft skills	Willingness to communicate Consideration of alternative perspectives Ability to evaluate benefits, risks and burdens Ability to cooperate in a group							
	Communication; Interpersonal; Problem solving;	Communication; Interpersonal;						
Process skills	Administrative Ability to manage group diversity	Administrative						
Emotional skills	Open minded Impartial Personal commitment Awareness of cultural factors influencing community							
	Emotional intelligence							41

Qualifications of EAU members

The table collects the main aspects of needed *qualifications* as observed/detailed in SATORI deliverables and the CWA (which is the basis for the standard of setting up and operating Ethics Committees on all levels of research ethics assessments).

Table 3.2.4. Qualifications required from EAU members

Stakeholders/members	Chairperson	Secretary	Field Practitioners	Ethics Specialists	Experts from various disciplines	Institutional Representatives	Legal experts	Public representatives
Experience	x	x	x	x	x	x	x	x
Certification								
Training	x	x	x		x	x		
University degree in ethics/law				x			x	

- Lay persons are defined as (from a skills point of view): “persons without relevant professional expertise to better reflect the social and cultural diversity of society” (CWA p.9)

- All members should be: “technically, ethically and administratively professional”(CWA p. 13) & competent (appropriate education; training and experience) (CWA p. 13.)

Summary of skills and qualifications

EAUs are comprised of different *types* of members; therefore each member needs different skills and qualifications. In general the chairperson is required to have a set of soft skills to swiftly manage process and team, while team members should have a mixture of soft and hard skills depending on their position/function within the EAU. In general, experience in ethics assessment processes is valued over qualification, and training is advised for all members. Specific knowledge/qualification is required for “ethics specialists” and “legal experts”.

Certification

Analysis of SATORI D.7.2. Exploring the potential of conformity assessment techniques to support ethics assessment pp.16-36.

A key question in reference to skills and qualifications of Ethics Committee members is the validation of such skills and qualifications. Certifications may be one potential form of validation. Need for certification is debated. Certifications may be offered to the process/procedure; the training provided or the person becoming a member of the committee.

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The table presents findings of issues related to certification:

What to certify?

Certification	YES	NO
Procedure	+++	
Training	++	
People	+	++

Potential certification of members of EAUs:

Benefits:

- Self-assessment
- Legal incentive
- Good for CV
- Improved personal marketability
- Industry benefit: quality enhancement

Hindrances:

- Hard to define “Ethics professional”
- Lack of demand and support
- Certain technological fields hard to standardize
- Varied by disciplines
- Monitoring is a problem
- Growing bureaucracy

Arguments for:

- Transparency
- Credibility
- Reliability
- Consistency
- Improvement in lack of specific qualifications
- Improvement in lack of specific education

Arguments against:

- Creating a two-class system
- Too much power to certain people
- Creating a tick-box exercise
- Different expertise needed
- EA is a citizen’s issue not a professional one

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Examples mentioned

- Compliance Certification Board (CCB) -- <http://www.compliancecertification.org/>

Types

- Conformity assessment (CA) – as demonstration that specified requirements relating to product, process, system, person, or body are fulfilled. Certification is one of the methods of demonstrating conformity. (.D.7.2. p. 20)

Issues related to certification:

- Certification procedure based on other EU examples: Regulation (EC) 1060/2009 – Committee of European Security Regulators; Directive 2007/59/EC certificates for train drivers; Regulation No 765/2008 Accreditation and market surveillance of products.
- Revocation and withdrawal of certification
- Harmonization with other CA/certifications in the EU

Summary of issues related to certification

Need for certification is debated. In general, procedure and training certification is favoured over personal certification. There are a number of risks and problems involved, however it is agreed that certification would improve trust, transparency and credibility of EAU.

Conclusion

A limited number of SATORI materials discuss skills, qualifications and the need for certification in ethics assessment processes. The general conclusion of the SATORI project in this regard is that “it would be premature to be too prescriptive. It should be up to the policy makers, associations of RECs and RECs (as users of the ethics assessment process) to determine (in consultation with standards and conformity assessment agencies) the best path forward.” (D7.2. p. 31.) ENERI as a project does exactly this. Regarding skills and qualifications: according to SATORI findings, experience in ethics assessment processes is valued over qualification; ethics training is advised for all members. Specific knowledge/qualification is required for “ethics specialists” and “legal experts”.

Regarding certification: procedure and training certification is favoured over personal certification; while there are a number of risks and problems involved in certification it is agreed that certification in some areas of EAU (mainly training and process) would improve trust, transparency and credibility. CWA and the EA framework delivered in SATORI should/could serve as a basis for such certification.

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MoRRI - Monitoring the Evolution and Benefits of Responsible Research and Innovation

MoRRI is a service that was set up in late 2014 and lasted until spring 2018. The project's main objective is "to provide scientific evidence, data, analysis and policy intelligence to directly support Directorate General for Research and Innovation (DG-RTD) research funding activities and policy-making activities in relation to Responsible Research and Innovation (RRI)". Expected results will be disseminated through annual monitoring reports on the developments of RRI dimensions, scientific notes that will address individual RRI dimensions and a summarising policy note. Furthermore there will be reports on RRI benefits and a final report. The project will use a mix of methods such as a literature review, interviews, case studies, surveys and it will explore future trends in a visioning workshop and discuss the outcomes in a larger dissemination context.

Document reviewed:

D2.4.1. Analytical report on the dimension of research and innovation ethics

Expertise as input for indicators/qualifications

The table collects the main aspects of needed *expertise* as observed/detailed in MORRI D2.4.1.

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Table 3.2.5. Examples of indicators/qualifications retrieved from MoRRI

Potential indicator/qualification	RI/RE related	Type of expertise (E.g. Educational, teaching, network etc.)	Organisational level of expertise (E.g. institutional, national, regional etc.)	Relevant scientific discipline (yes/no/specify)	Specific re-representation (E.g. type of stakeholder, ex. ministry, editor etc.)
	Ethics over science awareness	Soft laws and ethical codes	Institutional/different approaches to EA ie. Representation; deliberation; efficacy of output		Diversity of members advised as participatory process requirement

Summary

The literature review of ethics in MORRI focuses on the need and process of civic or lay participation in ethics assessment and advisory processes. As a general overview, the literature review demonstrates that democratic and participatory processes may be improved and would be beneficial to the social embeddedness of ethical aspects in R&I as opposed to a "closed", "elitist", only "expert" based approach to EA (p.53; p.64; p. 73; p.84-85; p. 87; p.90). This may have a bearing on the composition of EAUs (involving laypeople and

institutional stakeholder representatives) as well as on training and required qualification in deliberative and participatory approaches and processes.

PRINTEGER - Promoting Integrity as an Integral Dimension of Excellence in Research

PRINTEGER is a 36 month long project (01/09/2015 – 01/09/2018), with 8 partners from 7 countries. The project aims to improve adherence to high standards of integrity in research by improving integrity policies of national and international research organisations and by providing better tools for research leaders and managers. Additionally the project will contribute by improving ethical awareness and reflection through the education of new generations of scientists with next generation educational tools.

Documents reviewed:

- D2.3 Normative analysis
- D2.4 Legal analysis
- D2.6 Scientific misconduct and integrity: An organizational perspective
- D3.1 The extent and incidence of misconduct

Main observation

The documents available are mainly conceptual clarifications and theoretical discussions preparing for the empirical studies. Related to the ENERI Task 6.1, the documents reviewed do not contain any discussions regarding certification and qualifications/skills of ethics committee members.

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However, two themes in the documents reviewed indicate that the forthcoming empirical studies of the PRINTEGER project might provide relevant data/discussions for ENERI WP 6:

1. The organisation of commissions for handling misconduct

The document “D3.1 - The extent and incidence of misconduct” discusses how misconduct is handled at different institutions. It is highlighted that with the ambiguity over concepts, investigating and registering bodies define scientific integrity and scientific misconduct differently. The grey area of scientific misconduct is often settled informally, and hence rarely results in administrative procedures.

Further, comparing processes of handling misconduct across six countries, it is found that allegations of research misconduct are handled at different levels: responsibility can lie within the institution, with regional or national organizations, or through National Research Integrity Offices. Exactly what expertise and skills these bodies comprise is not discussed. The document is more focused on how investigating bodies handle their cases (how many misconduct notifications they register each year, the outcomes of these cases etc.). However, as expertise could be organised at different scales (institutional, regional and national), it is briefly mentioned that *‘compared a system of institutional bodies, National Integrity Offices are*

not always qualified to investigate the allegation if misconduct, and in some cases their competency is limited to providing an advice only' (p 9). From this, a simple table can be made:

Qualified to	Institutional commissions	National Integrity Offices
Investigate allegations	Yes	sometimes
Give advice	Sometimes	yes

For the ENERI task 6.1, it would have been interesting to see a further comparison of professional competences within these different investigating/registering bodies, and a comparison over general expertise (national scale) and expertise specialised into specific research fields (institutional scale). It is however unsure if PRINTEGERS forthcoming empirical studies will provide this information.

2. Forthcoming studies on how research organisations deal with integrity

Document D2.6 provides a theoretical discussion of a framework for studying the organisational responses to research misconduct, which will be applied in forthcoming empirical research. The concept of “*integrity work*” is promoted to investigate the ongoing organizational activities and strategies associated with developing, repairing and/or maintaining integrity. Three aspects are operationalized providing research questions for the empirical studies: *regulative* aspects like legislative frameworks, *normative* aspects like values and expectations, and *cognitive* aspects like culture and legitimization. These forthcoming empirical studies aiming to provide recommendations for organizational integrity work, might deliver possible indicators for evaluating the processes of improving research integrity competences.

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Conclusion

The PRINTEGER documents published so far do not discuss skills, qualifications and the need for certification in ethics assessment processes directly. This is because PRINTEGER is still in an early phase, and the empirical case studies are not yet completed. Especially two themes that will be empirically investigated in the forthcoming PRINTEGER research might provide relevant information for the ENERI WP 6: The comparison of institutional, regional and national committees across six countries, and the research on how specific organisations deal with integrity (integrity work).

3.3 Other empirical studies, reports and material on RE/RI qualifications

Research Ethics Committees (RECs) or Ethics Assessment Units (EAUs) (see above) are key drivers for promoting ethics in research and in assessing the ethical impacts of research, emerging technologies and innovation projects. Likewise, Research Integrity Offices (RIOs) and committees play a decisive role in promoting and upholding research integrity in their capacity of advising/instructing in current guidelines/regulations and in handling cases of scientific misconduct and questionable research practices. Due to their key and prevalent tasks in promoting RE/RI, this section will gather specific information on expert qualifications related to the type of expertise required for RECs and RIOs. Other important forms of RE/RI involvement is reviewed in section 4.

Research integrity committees at the national level

While RECs seem to be more established bodies internationally, cross-country systems for approaching research integrity appear more heterogeneous (Godecharle et al. 2013; European Science Foundation 2008). According to a comparison of RI systems for handling scientific misconduct in 15 different countries, three distinct roles can be identified: a) commissions can be tasked with an advisory role b) they can have decision-making power in specific cases or c) have the mandate to ‘supervise institutional processes’. A commission can be tasked with more than one of the stipulated roles (Danish Agency for Science and Higher Education 2015, 85-86). Additionally, the comparison shows that the composition of research integrity commissions vary between countries and in particular for commissions at the institutional level. For nationally established research integrity commissions, a few general characteristics of member composition can be identified:

- Members are appointed for a specific period of time, often between 2-4 years
- Members represents different research disciplines
- Members are highly acknowledged scholars
- Many national commissions have a legal expert appointed (often a judge),
- Some commissions can draw on international experts in specific cases (Danish Agency for Science and Higher Education 2015, 87)

In the revised Danish law concerning the Danish Committees for Scientific Dishonesty (DCSD), no particular collective nor individual skills and qualifications are emphasised besides from the requirement that members must be highly acknowledged scholars (Law no 383 of 26/04/2017). A review of the information provided by other national committees seems to support the observation that particular member skills and qualifications are not

specified. Examples include The Austrian Agency for Research Integrity⁸; The German Research Ombudsman⁹; The National Commission for the Investigation of Research Misconduct in Norway¹⁰, and the Finnish Advisory Board on Research Integrity (TENK)¹¹.

Research integrity committees at the institutional level

Research integrity committees and offices are increasingly being established at universities and research institutions worldwide, and procedures, strategy plans and guidelines have been produced to handle allegations of irresponsible research practices and/or advise on questions related to research integrity and ethics. As mentioned above, their composition and responsibilities may vary significantly among countries and institutions.

In the US, policies and procedures regarding misconduct in research are most often handled administratively by Research Integrity Offices or more specifically by Research Integrity Officers (RIO). The role of the RIO is not well-defined within a regulatory framework, but it often entails significant responsibilities and the functioning of being both ‘prosecutor, judge, mediator, counsellor, teacher and regulatory manager’ (Wright & Schneider 2010, 101). As to the collective and individual competences of RIO’s, Wright & Schneider emphasizes that ‘the RIO needs personal staff gifted in handling people and, ideally, staff with some training in forensics. Legal counsel, academic subject matters experts, IT experts, and a representative of institutional police or security are also key team members’ (2010, 106-107).

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In a study by the US Office of Research Integrity (ORI) on the ‘preparedness/readiness’ of US RIOs (ORI 2009), *personal characteristics* of relevance for job performance are conceptualised as:

- Behaviour: awareness about own performance and degree of satisfaction with one’s own performance
- ‘Degree and major field of study’
- Involvement in seeking research support
- Extent to which ‘the individual has been a principal investigator on a grant’
- Length of employment
- Self-identification as a researcher (ORI 2009, 25)

In terms of *experience*, the following conceptual variables are identified:

- Length of being an RIO

⁸ <http://www.oeawi.at/en/commission.asp>

⁹ <http://www.ombudsman-fuer-die-wissenschaft.de/?L=1>

¹⁰ <https://www.etikkom.no/en/our-work/about-us/the-national-commission-for-the-investigation-of-research-misconduct/about-the-national-commission-for-the-investigation-of-research-misconduct/>

¹¹ <http://www.tenk.fi/en/members>

- 'Whether the RIO has ever handled any allegations, directed an inquiry, or held an investigation of alleged research misconduct'
- Conference with other RIOs or ORI employees on managing 'hypothetical' cases
- Helped produce institutional policies and procedures (ORI 2009, 25-26)

Other countries operate with institutional integrity committees and have faculty advisors appointed to instruct employees in matters concerning research integrity. At Aarhus University such advisors 'must contribute to [the] instruction on research integrity and the responsible conduct of research, as well as monitoring developments in this area'¹².

At other universities, the personal competencies of Research Integrity Advisors (RIAs) is further specified. For instance, the Australian Catholic University and the University of Adelaide specifies the following requirements for Research Integrity Advisors (RIAs):

- 'Advisors of research integrity are expected to be experienced, independent senior mentors.
- Advisors should be people with research experience, wisdom, analytical skills, empathy, knowledge of the institution's policy and management structure, and familiarity with the accepted practices in research.
- RIAs will need to be fully aware of the requirements and responsibilities for the conduct of research as outlined in the Australian Code for the Responsible Conduct of Research'¹³.

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Research Ethics Committees

Most countries have established research ethics committees to review and monitor research projects, and in particular within the biomedical field of research. Despite cross-country difference concerning their legislative foundation, structure and practices (ENERI 2016, 9), RECs and the role of REC members seem more similar in composition and more well-defined compared to RIOs. In the UK, around 100 research ethics committees are established as independent bodies of the Health Research Authority. A committee consists of 7-15 lay and expert members. Expert members are required to be healthcare professionals with particular professional qualifications (hard skills). However, for both types of lay and expert members, a set of essential qualities are required in order to be appointed (soft, process and emotional skills). These required skills are stipulated in table 3.3.1. below.

Table 3.3.1. Essential qualities required for the role of lay and expert members in NHS RECs

¹² <http://www.au.dk/en/research/responsible-conduct-of-research/advisers/>

¹³

http://www.acu.edu.au/research/current_research_students/forms_and_policies2/policies/role_of_research_integrity_advisors; <http://www.adelaide.edu.au/research-services/oreci/integrity/advisors/>

You should:

- have a strong personal commitment to the interests of patients who take part (or are asked to) in health care research;
- have a strong personal commitment to ensuring the highest standards for health care research;
- be able to read, understand and analyse complex issues from research proposals and weigh up conflicting opinions
- be able to take an objective stance, looking at a situation from several perspectives;
- be a good communicator with a practical approach and confidence to voice your opinions;
- be able to discuss issues with people who may not agree with you including being able to influence others from a range of backgrounds;
- be committed to the public service values of accountability, probity, openness and equality of opportunity;
- be able to demonstrate an ability to contribute to the work of the REC;
- be available monthly (approximately 10 meetings per year) with a commitment to attend at least 6 of the meetings;
- be available to undertake the review of Proportionate Review applications and substantial amendments electronically on a rota basis;
- understand the requirement for confidentiality in issues faced by a REC;
- be willing to undertake initial induction training and then at least 5 hours training per year to equip you to carry out your role;
- be IT literate and have access to a computer or tablet to allow some REC work to be carried out via email and via the Member Portal.

Source: Information for potential Research Ethics Service Committee members. Standard Application Pack all members (HRA) version 2.0, December 2015. NHS. Available at: <http://www.hra.nhs.uk/documents/2015/12/standard-application-pack-rec-members.pdf>

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Other research ethics committees do not specify member qualities to the extent above, but state in more general terms the requirements of proper academic training and experience; expectations to collective responsibilities and to the composition of the committee (i.e. division between lay and expert, gender balance, geographical distribution). The Danish legislative basis for REC's constitutes one such example¹⁴.

The Steering Committee on Bioethics (CDBI) of the Council of Europe has produced a 'Guide for Research Ethics Committee Members' (2010) which intends to act as an instrument for REC members within the biomedical research field. In terms of member qualities, the guidelines add to the more generic description in the section above and specifies that:

'REC members should have a basic understanding of the importance of research and how it can benefit human health and welfare. They should be able to understand the principles of research and research methods, the research context, and the practicalities of carrying out biomedical research. They must be

¹⁴ Law no 593 of 14/06/2011, available at <https://www.retsinformation.dk/Forms/R0710.aspx?id=137674>

able to make their own independent judgements when considering the ethical issues involved in the research proposals placed before them' (Council of Europe 2010).

As in the NHS' guidelines, the Steering Committee on Bioethics stresses the importance of initial and ongoing training of REC members.

4. Identification of key forums/formats for practising RE/RI

The following section identifies main formats and mechanisms for incorporating and promoting ethical and integrity concerns in research. The main aim is to locate other types of involvement in RI/RE than RECs and RIOs and, if obtainable, identify existing types of RI/RE competencies, criteria, and qualifications requested at different organisational levels (e.g. institutional, national, regional) and in terms of different kinds of representation/stakeholder (e.g. committee member, ministry representative, editor etc.). These findings are assembled and presented in table 4.1 below.

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Table 4.1. different types of RE/RI involvement

Type of involvement	Type of representation (legal experts, chair, RI officer etc.)	Type of experience (educational, administrative, network etc.)	Skills required (hard, soft, process, emotional skills)	Organisational level of expertise (institutional, national, regional, international)	Scientific discipline	Description of skills/expertise	Source(s)
Research ethics committees at research performing organisations				institutional			D2.4.1. (MoRRi) IAP (2012)
Research ethics committees at research funding organisations			Proper skills and knowledge; sensitivity to the research context	national international			D2.4.1. (MoRRi) Economic and Social Research council (http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/our-commitment/)
Ethics Advisory Committees providing advice to				national			D2.4.1. (MoRRi)

governments and parliaments							
RI/RE Consultants/advisors in Ministries				national			
Consultants/advisors at European and international RI/RE organisations/networks (e.g. ALLEA, ENRIO, EUREC)				international			
Institutions governing academic integrity				National International			D2.4.1. (MoRRi)
		Involvement in national and European projects on research ethics, responsibility and integrity					
		Scientific production of articles on ethics, responsibility and integrity topics					
		Experiences with design and implementation of RE/RI training activities					
		legal/administrative RE/RI experiences (concerning open access; technology transfer/assessment etc.					
Science journalist specialized in Ethics/integrity issues							
Advisor/consultant on							

corporate social responsibility/ corporate sustainability							
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In general, only a limited amount of resources exist that detail existing and potential expert qualifications related to involvement in research ethics and research integrity. This seems particularly to be the case in the types of RE/RI involvement that extends beyond RECs and RIO's. Furthermore, in terms of the material reviewed for this report, expert qualifications seem more often to be stipulated at a collective level of expertise rather than at the individual level.

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6. Further information

SATORI

Members of the EAUs¹⁵

EAUs consist of various types of members: a chairperson, field practitioners, ethics specialists, experts from other disciplines, institutional representatives, legal experts, public representatives and members of the public (including laypersons and end-user(s), or representative(s) of the end-user group(s) or organization(s)). The information used to develop this categorisation is contained in the ethics assessment reports within Annex 3 of SATORI Deliverable D1.1.¹⁶

The Chairperson

The chairperson represents the EAU in official communications and is responsible for organising and arranging the meetings of the group's members. Chairpersons are also responsible for the smooth operation of the EAU's deliberations and the timely completion and reporting of the group's decisions.

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The person selected for this task should possess strong administrative competence. This competence includes the interpersonal skills in fostering productive group discussions and in ensuring that the various members of the EAU are able to contribute to the group's deliberations effectively.¹⁷ The chairperson should also be responsible for ensuring that members receive any training they may require to fulfil their role.¹⁸

The Secretary

The secretary of an EAU is responsible for the administrative and bureaucratic functions of the unit. Secretaries organise the practical details of the EAU's function, such as arranging meetings, receiving proposals and distributing them to members for assessment, and acting as a point of contact between the EAU and those outside of the unit. The secretary also makes

¹⁵ Philip Jansen, Wessel Reijers, David Douglas, Agata Gurzawska, Alexandra Kapeller & Philip Brey, Rok Benčin, Zuzanna Warso: *SATORI Deliverable D4.1 A reasoned proposal for shared approaches to ethics assessment in the European context*, December, 2016, pp. 89-90.

¹⁶ Shelley-Egan, Clare, Philip Brey, Rowena Rodrigues, David Douglas, Agata Gurzawska, Lise Bitsch, David Wright & Kush Wadhwa, *SATORI Deliverable D1.1 Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries*, June 2015. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf ; "Comparative Analysis of Ethics Assessment Practices." *SATORI*, June 2015. http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/.

¹⁷ Ryan, Mary Kay, "General Organization of the IRB", in Robert A. Greenwald, Mary Kay Ryan, and James E. Mulvihill (eds.), *Human Subjects Research: A Handbook for Institutional Review Boards*, Plenum Press, New York and London, 1982, pp. 29–38 [p. 32].

¹⁸ Ibid.

notes of EAU meetings and decisions and distributes them to members so that there is a record of their deliberations.

Like the chairperson, the person selected to be the secretary should possess strong administrative competence. Good communication skills assist the chairperson in assuring researchers that the EAU's procedures are clear and unbiased. Similarly, the chairperson's communication skills contribute to explaining and justifying the EAU's decisions to researchers in a respectful manner. Good record keeping of the EAU's deliberations and decisions will assist in achieving these goals.

Field practitioners

Field practitioners possess expertise relevant to the R&I activity the EAU reviews. The specific expertise is often connected with the role of the institution associated with the EAU. For example, physicians, pharmacists, and nurses may belong to a hospital EAU.

Ethics specialists

Ethical specialists have expertise in evaluating moral issues and who are sought after for moral advice. This category includes religious leaders or representatives as well as ethicists and philosophers.

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Experts from other disciplines

Sometimes practitioners and experts from fields not directly related to the work under review are included in an EAU. They serve a similar function to lay persons on EAUs in that they bring an outside perspective (i.e. one from outside the particular R&I field) to the EAU's assessment. Unlike lay persons, however, experts from other disciplines are included primarily for their professional expertise that is *indirectly* relevant to the R&I activity being assessed. For example, sociologists may belong to a medical ethics committee to provide expertise on the relevant social factors associated with medicine and medical care.

Institutional representatives

Members of the institution associated with the ethics assessor are also common members. For example, university EAUs may include faculty members, administrative staff, PhD candidates, and student representatives.

Legal experts

Lawyers and those with legal expertise are valuable for ensuring that the work reviewed by an EAU meets any legal requirements and legislation that affect it. Including legal experts is important for protecting the legal rights of human participants and for complying with the regulations concerning animal experimentations and other biological research. Legal expertise also helps to identify legal problems that might arise for the researchers and their institution if particular R&I activity is performed which does not comply with the relevant laws and regulations.

Public representatives/Members of the Public

R&I activity may affect the public directly (as research participants) or indirectly by the effects new developments have within society. Public representatives in EAUs represent the interests of non-experts in discussions. This representation may take the form of lay persons, patient or participant advocates, or members of civil society organisations and NGOs such as animal welfare or environmental protection groups. Lay persons may be considered as having expertise ‘about the “community” of nonscientists in general’.¹⁹ End- users, or representative of the end- user groups or organization, patient advocates represent the interests of those whose medical care is affected by the proposed research.

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Skills and expertise of EAU members²⁰

- The membership of an EAU should be arranged so that it encourages rigorous discussion and evaluation of R&I activity. This is best achieved by a membership that is *competent* (technically, ethically, and administratively), *independent* of the researchers and the institutions involved, *diverse* in backgrounds and expertise, and *representative* of the communities affected by its decisions.
- The EAU chairperson should possess strong administrative competence. This includes good interpersonal skills for managing group decisions and good communication skills to convey the EAU’s decisions to researchers and supervisors.
- Those with expertise relevant to the activity under review should be included among the EAU’s members. However, persons without directly relevant expertise should be an equally important section of the membership.
- EAU members should possess the following characteristics:
 - Relevant expertise (professional members) or an informed interest (non-professional members/lay persons, experts from other fields) in the R&I activity under assessment
 - Good communication skills, both written and interpersonal

¹⁹ Solomon, Stephanie, “Too Many Rationales, Not Enough Reason: A Call to Examine the Goals of Including Lay Members on Institutional Review Boards”, *Accountability in Research*, Vol. 23, No. 1, January 2016, pp. 4–22 [p. 15].

²⁰ Philip Jansen, Wessel Reijers, David Douglas, Agata Gurzawska, Alexandra Kapeller & Philip Brey, Rok Benčin, Zuzanna Warso: *SATORI Deliverable D4.1 A reasoned proposal for shared approaches to ethics assessment in the European context*, December, 2016. p. 95.

- An ability to evaluate the benefits, risks, and burdens associated with the specific research projects assessed
- An ability to engage in reasoned debate and discussion to reach and accept a balanced view of the research projects assessed
- Personal commitment to the goals of ethics assessment

Qualifications of EAU members

“One interviewee acknowledged that ethics professionals should be qualified, but added that experience, such as experience sitting on ethics committees, would be superior to formal training.”²¹

²¹ Rowena Rodrigues, Michael Madary, Andrea Porcari, Elvio Mantovani: SATORI Deliverable 7.2. Exploring the potential of conformity assessment techniques to support ethics assessment, February, 2017.

Appendix 2. Expert interview study

RI/RE expert qualifications

Results from a qualitative expert interview study

ENERI, WP6, 6.1

2017

Tine Ravn, Robert Braun & Helmut Hönigsmayer

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1. Summary

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. Work package 6 addresses the main objective in the project “to create an e-community/database (...) of European and whenever relevant international experts in the different fields of research ethics and integrity”, which “should notably ensure the certification of the knowledge level of the experts” The main objectives are (1) to explore and develop indicators that are widely accepted in the heterogeneous field of RE/RI representing expertise in the two areas to be implemented in the expert data base; (2) to evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly; and (3) address the construction, mapping, and monitoring of central expert criteria.

Database design:

- Broad agreement among experts concerning the valuable aspect of establishing a database, adopting an inclusive, diverse and transparent approach to RE/RI expertise.
- For the next steps in the empirical programme, the expert interviewees raise a number of discussion points and themes valuable for further exploration:
 - The character of specific database objectives and key user needs
 - The structure and particular design of individual expert profiles (number of pre-defined and standardized categories, items, descriptions etc.)
 - Registration of experts (open access, management entry and monitoring, nomination procedure etc.)

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Skills and qualifications:

- Most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise, holding that such expertise can take many forms (expert types, RE/RI topics, organisational levels etc.) Formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria.
- Softer and emotional skills are highly prioritized. Expert interviews show that such skills need to feature into the individual database profiles and into the final sets of criteria/indicators in some form.

Access database training & certification:

- An optional training course before database entering might be relevant, but a majority of interviewees would not make it mandatory. Several also question how to design a standardised course that would work as a common expert foundation.
- A few experts see a personal issued database certification as a good idea. Several view it as acceptable, but find it difficult to see its real value and the incentives for issuing one.
- The issue of training requirements and the issue of issuing a personal certification do not yet yield clear recommendations.
- The pros and cons of issuing a personal certification for database membership are not conclusive based on the interview study; the topic could be a prospect for further assessment.

Potential questions to be decided upon in the consensus conference series:

- Agreement
 - on the definition of database objectives and key user needs;
 - on structure and particular design of individual expert profiles;
 - on format of registration of experts;
 - on general approach to RE/RI expertise;
 - on formal and relevant education, RE/RI experience;
 - on optional training course;
 - on database certification;
 - on personal certification.

2. Introduction

Research integrity (i.e. professional standards of conducting research) and research ethics (i.e. moral principles embedded in research) are pertinent topics in scientific research. Certainly, issues of research ethics (RE) and research integrity (RI) have always been inextricably linked with scientific processes. However, the changing and globalized nature of science in terms of techno-scientific innovations have given rise to new risks and ethical questions. Research infrastructures (i.e. funding and performance structures, journal and review systems, administration etc.) have been transformed and have - together with a rising number of cases of research misconduct (Anderson et al. 2013; Steneck 2006) - resulted in a greater need for the production and exchange of knowledge on how to practice, govern and fund sound and responsible research (IAP 2012; Ravn, Braun & Drivdal 2017).

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. It is the ambition that such a shared platform - comprised of expert networks and groups, ethics and integrity commissions, assessment boards and expert databases etc. - may serve as a tool for promoting awareness and exchanging and disseminating knowledge, as well as substantiating and harmonizing cross-country experiences, standards, guidelines and 'best practices' within the fields of research ethics and research integrity.

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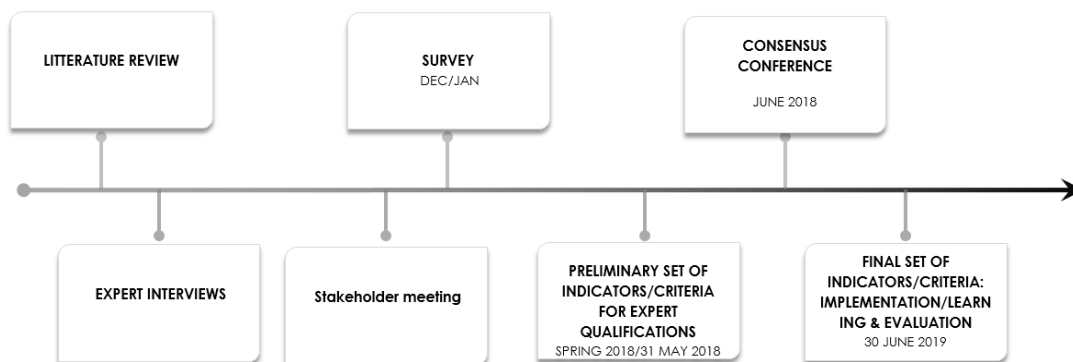
Specifically, work package 6 (WP6) in ENERI addresses the main objective in the project "to create an e-community/database (...) of European and whenever relevant, international experts, in the different fields of research ethics and integrity", which "should notably ensure the certification of the knowledge level of the experts" (ENERI 2016, 40). Following this objective, it is stated that "an essential precondition for setting up and running this database is a meaningful as well as widely accepted definition of criteria that constitute expertise in the fields of research integrity and ethics" (ENERI 2016, 40). The main objectives in this regard are:

- To explore and develop indicators that are widely accepted in the heterogeneous field of RE/RI representing expertise in the two areas to be implemented in the expert data base

- To evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly

Hence, the key tasks are to certify experts and develop indicators to address the construction, mapping, and monitoring of central expert criteria. To explore how such criteria are to be defined and how RE/RI expertise is to be constituted, an initial literature review is conducted with the objective to review, map and assess existing literature, reports and European projects concerning potential expert qualifications/indicators (for the report see Ravn, Braun & Drivdal 2017). An empirical programme consisting of interviews with selected experts and an online survey that targets a variety of actors, stakeholders and organizations follows the literature review. As depicted in figure 1 below, the process of identifying, exploring and conducting expert indicators and criteria involves an initial stakeholder meeting and subsequent mid-term consensus conference, in order to discuss the preliminary set of RE/RI indicators and particular database objectives/design matters.

Figure 1. Overview of ENERI, WP6



The report at hand details the results from the expert interview study as well as key discussion points/results from the initial stakeholder conference. The expert interview study includes semi-structured interviews with 12 different research ethics and/or research integrity experts across Europe and across different institutional categories (see section below).

3. Methods and approach

The main reasons for opting for expert interviews as a first data collection source are to a) open up the heterogeneous fields of research ethics and research integrity, b) to inductively explore and generate knowledge on potential RE/RI expert criteria from a variety of key representatives and c) to collect contextual information that may complement insights and inform the remaining empirical programme.

In terms of generating new knowledge, the expert interview guide is constructed with a dual focus. The first part of the interview focuses on the particular interviewees' experiences and perceptions of key research integrity/ethics qualifications and skills in their own capacity as experts and from the vantage point of their own institution/organisation/network/committee. A question could for instance relate to which kind of existing skills and competences they regard to be the most important to e.g. their roles as REC members, or to their capacity as industrial or funding agency representatives etc. The second part of the interview addresses interviewees' perception of more general research integrity/ethics skills and qualifications concerning the expert database/e-community to be established by the project and EU commission. Interview focus areas in this regard is on database objectives, expert 'membership' criteria, RE/RI training possibilities and issues of certification (see interview guide, appendix A for details).

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All expert interviews have been conducted in September and primo October 2017; 11 interviews were performed by phone or skype and the last interview was performed face-to-face. The interviews last between 30-60 minutes approximately. All interviewees were recruited via a personal email invitation (see appendix B) and interview appointments have subsequently been agreed upon through direct email correspondence.

The selection of experts/interviewees is based on an 'information oriented' (Bo 2005, 71) selection strategy, with the aim of reaching a broad group of RE/RI experts and to achieve variation according to the 'criteria of maximum variation' (Bo 2005, 72) and thus enhance in-depth understandings of potential expert criteria and qualifications. Variation has been pursued according to the following criteria: research ethics/research integrity focus; institutional category, geographical location, gender and age.

The institutional category endeavoured to include the following types of representation and experts positioned in:

- National research ethics committees (REC)
- Regional/local research committees (REC)
- European network of RECs (EUREC)
- National research integrity committees/offices (RIO)
- Local/university research integrity committees/offices (RIO)
- European network of research integrity offices (ENRIO)
- National funding organization (involved in ethics review)
- European funding organization (involved in ethics review)
- Government agency (ministry)
- Industrial advisor/consultant on ethics/CSR/corporate sustainability
- Research with expertise within the field of RE
- Research with expertise within the field of RIO

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Hence, despite a relatively small interview sample, the sample strategy allows for a certain amount of variation and geographical and institutional distribution due to the experts' particular experiences/institutional affiliation and their meeting of relevant criteria of relevance for the objectives of the interview study. For the list of experts and their geographical, institutional and RE/RI expertise, see appendix C. The participating interviewees represent most of the pre-defined categories; however, a few interviewees represent more than one type of representation, and for this reason different emphasis is given to these expert roles in their interviews. Furthermore, interviewees have signed an informed consent template, see appendix D.

Interviews have been recorded and subsequently transcribed verbatim by student assistants. All interviews have then been coded thematically in the software programme Nvivo, which allows for a transparent and comparable management and analysis of the empirical data. Interviews have been coded according to a structured coding strategy in alignment with the set of focused codes derived from the key themes explored in the interviews. Notwithstanding, this coding strategy was combined with the process of initial coding (Charmaz 2006) that allows for an empirically grounded approach at where new themes/attention points are explored in an open manner.

The following sections will summarize and present the main results, discussions and attention points raised by the research ethics and – integrity experts. The first section explores the theme of database objectives, which exemplifies a substantial theme that primarily arose during the interviews as opposed to being a pre-defined interview subject.

3. Results from the expert interview study

3.1. Database objectives

The pre-defined objectives of the database are broadly characterized as constructing a database of international experts within the fields of research ethics and research integrity. A secondary aim of the database construction is to serve as a platform for creating an ‘e-community’ of experts in order to strengthen professional networks across relevant fields, disciplines and institutional representation as well as the interaction between relevant areas of RE and RI. In the expert interviews, several informants explicitly asked for specific database objectives, in order to provide the most effective and valuable database design recommendations. Similar calls for clearly defined objectives and user specifications were also raised in the stakeholder meeting (see section 4). While the process of constructing RI/RE qualification indicators and building a proper database design benefits from an open, generative and exploratory process, expert and stakeholder recommendations reveal a need to explicitly explore and identify particular user groups and their particular needs and wants for a database in the subsequent survey questions.

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Based on the pre-defined database objectives, the potential value and use of an international expert database is clearly expressed; there is wide agreement that such a database might provide a useful platform to: “harmonize different national contact points” (Rouby, p. 16) and function as a common ground for knowledge exchange. The database is also viewed as a source of information where relevant experts and stakeholders can be identified when assembling review panels, misconduct committees or constructing local, regional, and national policy guidelines etc.

Furthermore, it is evident from the interviews that experts recommend the database to be open and inclusive and that it be designed to allow for a transparent and diverse approach to expert qualifications and criteria, avoiding “the usual suspects” and “just consolidating the ivory tower of ethical expertise” (Dratwa, p. 11) as one expert points out. In this regard, several interviewees point to the valuable aspect of making it easier to keep track of relevant

stakeholders and to “find the right people” (Hiney, p. 16) in terms of expanding one’s search for relevant expertise beyond familiar networks and national/international known experts.

Two experts also explicitly give words to the changeable and contingent nature of the fields of RE/RI (and science more in general) and the ephemeral notion of what constitutes expertise within a given time frame and within different cultural, geographical and epistemic contexts etc. Both argue that the database should be approached as a “living organism” (Dubravka, p.10) and that the guiding principle of expertise behind it should originate from a multidisciplinary, inclusive and broad perspective that may “give room to other ways of showing expertise” (Rauhala, p. 16). In this regard, the latter expert also suggests making use of self-descriptions to allow expert members to describe their current and particular areas of expertise along with relevant experiences and preferred ways of working, for instance (p.9). This idea is also explicitly supported by a third expert, who suggests that the database features a “free-style box”, in which to specify involvement in “local/national/international committees and working groups”, for instance, in the individual expert profiles (Hiney, p. 9). Furthermore, the last-mentioned expert also provides a set of explicit recommendations on how to structure and stratify the database. One can easily end up with a great number of main- and sub classifications as she points out, and she suggests to only include “fairly broad classifications” which stratify in terms of *type* (for instance practitioners, policy experts, academic experts), particular sets of *experience* and by specific *topics* (for instance publication ethics, types of misconduct, data management and development of teaching curricula) (Hiney, p. 6-8).

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The issue of how to design the database is closely interlinked with the question of what constitutes RE/RI expertise and qualifications; while as an independent subject specific design issues such as registration, number of categories/items/descriptions and so forth are more sporadically taken up in the interviews. Therefore, such design issues are in and of themselves a very relevant subject for further survey exploration. As mentioned above, some experts recommend a semi-structured profile design, whereas one expert prefers a “deeply structured” strategy to avoid a “phonebook” set-up (Claesen, p. 5). Another issue for further assessment concerns how expert members are to register into the database. One expert explicitly recommends a nomination strategy where “we collect [expert] suggestions from competent national bodies, which we have faith in” (Madsen, p. 12). Hence, the question of database openness – a feature that many experts underscore – remains to be further explored in terms of access and registration.

3.1.1 Recapturing points

- Broad agreement among experts concerning the valuable aspect of establishing a database, which adopt an inclusive, diverse and transparent approach to RE/RI expertise.
- For the next steps in the empirical programme, the expert interviewees raise a number of discussion points and themes valuable for further exploration:
 - The character of specific database objectives and key user needs
 - The structure and particular design of individual expert profiles (number of pre-defined and standardized categories, items, descriptions etc.)
 - Registration of experts (open access, management entry and monitoring, nomination procedure etc.)

3.2. RI/RE skills and qualifications

The expert interviews speak both to the issue of particular RI/RE skills and qualifications from the part of the individual experts and his/her institution, as well as the experts' views on relevant sets of database expertise. Despite variation, the statements, discussions, and recommendations that emerge from the interviews centre on the core questions of what constitutes an 'expert': are expert criteria defined by specific types of education, years of practical experience, teaching experience or analytical, administrative or interpersonal skills, for instance? Who is to define expertise? Furthermore, to which degree is it possible – and not least suitable and desirable – to standardise RE/RI expert qualifications?

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As a general impression, interviewees seem to share a general consensus as to the rather nebulous and indefinable notion of what RE/RI expertise is, with interviewees agreeing on a series of key points. There are many types of experts (such as practitioners, policy/law experts, academic experts etc.). Expertise can be possessed within a large number of RE/RI topics (such as publication ethics, codes of conduct, ethics review, data management, FFP, QRPs, teaching curriculum development, bibliometric etc.) and expertise may relate to one or several organizational levels (e.g. local, regional, national, European or international areas of knowledge). Moreover, while expert interviewees provide explicit examples of core competences and skills in regard to their own position and to the database, it is also evident that no fixed expertise definition exists and that RE/RI qualifications, in many ways, can be regarded as intrinsic to research processes and may occur as a kind of tacit knowledge (Polanyi, 1958). This seems to be particularly the case for the field of research integrity which – compared to the field of research ethics – appear less established in terms of the production of in- and cross-country legislation and in regard to instituted procedures, guidelines and

university courses specifying professional standards of conducting research (see also Ravn, Braun & Drivdal 2017).

Furthermore, the academic breath, complexity and multidisciplinary of both fields add to the challenge of stipulating clear expertise standards for RE/RI skills and competences. In this regard, most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise, highlighting the benefits of collective skills on the one hand, and highly specialised areas of expertise on the other. Then, from a broad perspective, interviewees emphasise formal education and relevant experience as the most important competences. Training in ethics/integrity issues are relevant, but several experts point out that the completion of a formal course in research ethics or integrity do not make one an expert in such areas. They highlight seniority (or similar well established) experience within a given area of expertise as the most important competence, in combination with a relevant formal education. In addition to such competences, interviewees underline an array of core skills relevant for their type of RE/RI involvement/representation. These are shown in table 3.2.1. below, along with organisational levels of expertise, skills that could be further pursued and potential frictions between currently employed qualifications.

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3.2.1. Interviewees' institution – competences and skills

Table 3.2.1. Core competences and skills related to different types of RE/RI representation

Type of RI/RI involvement	Type of representation (legal experts, chair, RI officer etc.)	Type of experience/competences (educational, administrative, network etc.)	Skills required (hard, soft, process, emotional skills)	Organisational level of expertise (institutional, national, regional, international)	Further pursuing of skills	Frictions among skills	Source(s)
Ethics expert in H2020	Ethical appraisal/review	Formal education – competences in ethics “guidelines, rulebooks, recommendations” (p.2) Research experience	Communication- al skills Interpersonal Open- mindedness Critical thinking Independence Analytical skills Eye for details	European			Vejnovic, p. 2-4
University RIO	Head of committee	Deep knowledge of RE/RI issues Senior scientific experience	Scientific skills/integrity Committee members: Process skills Named persons: interpersonal skills	institutional		Discipline differences	Madsen, p. 1, 7

European Association of research managers and administrators	Managing director	Knowledge of ethics + national/international guidelines,	Communication- al skills Research skills	European			Claesen p. 1-2
National funding org.	Head of unit	Formal education Ethical competences		National			Hiney p. 9
European funding org.	Head of European Group on Ethics in Science and New Technologies	Member composition: discipline and expertise diversity Gender, geographical prominence, age, institutional background	Thinking “outside the institutional buzz” (p.3) interpersonal and emotional skills Process skills Deliberation Open-mindedness “skills of peace-making, conflict-resolution, negotiations” (p. 6) Turning ideas into recommendation	European			Dratwa p. 3-4
Permanent Working Party of Research Ethics Committees	Co-founder	As a researcher fulfill: “scientific quality, conformity with law and ethical acceptability” (Doppelfeldt p. 1)	Researcher: commitment to publication (p.2) Societal/health care awareness/ impact Ethic commitment Ethical thinking	National		Contradictions in terms of normative ethics	Doppelfeldt p.3-5
National REC	Director	Ethical and legal expertise Professional qualifications	For committee members: Ethic skills Interpersonal (communication al, deliberation) Open-mindedness Societal awareness	National		Discipline differences	Ingierd p. 4, 5, 7
Journal editor	Administrative	Policy guidelines Codes of conduct		International			Marusic, p. 3,
Academic expertise in RE and RI	Researcher	Education and practice (both at an individual and institutional level)		National International	Clearer/detailed institutional guidelines /frameworks	Pressure to publish	Marusic, p. 5-6
	Ethics advisor	Research ethics competences Scientific awareness/understanding	Personal commitment Communication- al skills				Rauhala p. 3, 5, 6

Industrial advisor		Scientific education (master level minimum)	Collaboration skills "listen to different perspectives and taking into account the needs of different domains" (p.6) Decision-making skills	National international	Promote openness and transparency + towards negative results	Drive to get positive results and also trustworthy results Pressure to publish (medical/collective success and not just individual)	Gilis, p. 6, 9-10
National funding org.	Legal	Guidelines of soft law Insights into International practices and guidelines Ethics assessment/review competences/knowledge of good scientific practices Transparent, impersonal, confidential treatment of funding proposals Seniority experience	"understand the needs of other stakeholders", p.4 Cultural awareness	National European		Cross-country variation in RI definitions	Rouby, p. 4, 7

As shown in the table above, different types of experts highlight different types of experience and competences in accordance with their field of expertise and RE/RI representation. Hence, ethics assessment/review competences are emphasized for ethics research projects reviewers, while knowledge of integrity guidelines and codes of conduct are mentioned as important competences for journal editors, for instance. Despite variation, similarities as to core competences and skills appear somewhat consistent across different areas of expertise. Regarding competences, the following types of acquired knowledge are suggested:

- Ethical competences (deep knowledge of national and international regulation, policy and guidelines)
- Integrity competences (deep knowledge of national and international regulation, policy and guidelines)

- Research/science competences (research experience)
- Legal competences
- Ethics assessment/review competences
- Integrity assessment/review competences

Experts agree on the importance of a number of skills related to communication, deliberation, collaboration and management, among others. Below, these are summarized and grouped according to hard skills (e.g. education, technical), soft skills (e.g. communicative), process skills (e.g. administrative/management) and emotional skills (commitment, open mindedness).

Hard skills:

- Analytical skills
- Scientific skills
- Ethical commitment/thinking/abilities
- Critical thinking
- Assessment/ review

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Soft skills:

- Communicational
- Interpersonal
- Eye for details
- Deliberation
- Peace-making, conflict-resolution
- Collaboration

Process skills:

- Administrative/management
- Turning ideas into recommendations/practice
- Decision-making

Emotional skills:

- Open-mindedness
- Independence
- Societal/cultural/health care awareness/impact

- Personal commitment

Regardless of RE/RI expertise type, experts emphasize and prioritize a host of emotional skills as essential for working with and within areas related to research ethics and integrity. Being open-minded towards other perspectives, as well as able to collaborate, for instance, is seen to minimize potential frictions between different discipline practices/guidelines etc. and more broadly between different (normative) perceptions of ethical/integrity standards across research fields, institutions and countries, among others.

3.2.2 Database expert competences and skills

The interviewees' recommendations for relevant database expert competences and skills are very similar to those mentioned in terms of their own/institutional/organizational sets of expert criteria. A broad, multidisciplinary and inclusive approach to RI/RE expertise are once more highlighted as well as the general competences of relevant formal education and recognized/profound RI/RE experience are perceived to be the most important competences. Soft and emotional skills, such as open mindedness and the ability to discuss in a multidisciplinary fashion are also mentioned as criteria for the inclusion of a database expert. Furthermore, one expert also points to the importance of ensuring that database members do not have any conflict of interest in roles as experts (Rouby, p. 10).

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Different types of experts are mentioned as potential candidates for the database: experts with an “omnibus” function; local and national RIO's, researchers in RE/RI; medical researchers; REC members; editors; publishers; individuals with national/EU project evaluation/review experience; RE/RI university teachers; research funders; RE/RI communication trained individuals; specialists in constitutional law/applied ethics/philosophy/social science/psychology/economy/criminology; practitioner network members (e.g. ENRIO); RE/RI policy experts. A few interviewees furthermore mention that lay people might be relevant to include in the database similar to the composition of REC's.

3.2.3 Summary of main points

- Most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise, holding that such expertise can take many forms (expert types, RE/RI topics, organisational levels etc.)
- Formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria.
- Softer and emotional skills are highly prioritized, too. While these “are very difficult to quantify” (Rauhala, p. 15), the expert interviews show that such skills need to

feature into the individual database profiles and into the final sets of criteria/indicators in some form.

3.3 Database training and certification

3.1.1 Access training course

Interviewees are asked to assess whether they would recommend potential database experts to undergo an initial research ethics/integrity training programme in order to become members. While a majority of interviewees find initial – but optional – training relevant, several interviewees express scepticism about the design of a “standard course” and its ability to provide relevant introductory content for all kinds of experts, arguing that such a course “is not a guarantee that you get people that know their job” (Rauhala, p. 13) since expertise is primarily “experience-based” (Rauhala p. 14). Another expert points to the issue of “who should have the authority to sort of say that ‘this is what you should do and what you should know’” (Claesen p. 6). The latter expert does however recommend some kind of initial and objective quality assurance/testing mechanism to verify member expertise (p. 6-7).

Two interviewees explicitly recommend an introductory training course to be mandatory to make sure experts are “at the same kind of starting level” (Marusic, p. 10) and because:

“... our countries are different, we have a different ways of dealing with things, and then it is good to have that, we were talking about this standardized training. So in that way all experts in the database will be communicating the same language or the same level, at least at the start” (Vejnovic, p. 7).

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Both of the above-mentioned experts, along with one additional expert, are also in favour of a personal training certificate to be issued after course completion. The majority of interviewees are not in favour of a mandatory course, primarily because potential member experts are already perceived to be expert representatives of their respective fields (Gilis, p. 13) and because it would discourage qualified and busy experts from becoming members (Doppelfeldt, p. 10; Madsen, p. 11).

3.1.2 Certification

In the expert interviews it is discussed whether a form of personal certification should be issued to members of the database as a validation of RE/RI skills and competences. Expert opinions, however, are divided. Only a few interviewees explicitly express a particularly positive view of personal certification, with one arguing that it might be a credential to use internationally and outside of one’s research institution. Several experts state that a personal certification would be acceptable, but find it rather difficult to see the clear benefits and incentives. Such difficulties also relate to the issue of expertise standardisation and to the

objectives of the database. One expert suggests that it could “increase visibility of the [European integrity] network in the database to give a special voucher or special part, a special additional line that can be put on to the CV” but that it at the same time “would be sort of a proxy for the fact that they followed a certification” (Dratwa, p. 10). Nonetheless, the pros and cons of issuing a personal certification for database membership are not conclusive, based on the interview study, and the topic could probably be a prospect for further assessment.

3.1.3 Summary of main points

- An optional training course before database entering might be relevant, but a majority of interviewees would not make it mandatory. Several also question how to design a standardised course that would work as a common expert foundation.
- A few experts see a personal issued database certification as a good idea. Several view it as acceptable, but find it difficult to see its real value and the incentives for issuing one.
- The issue of training requirements and the issue of issuing a personal certification do not yield clear recommendations. Both issues would be highly relevant to pursue in the subsequent empirical programme (survey and consensus conference).

4. Results from the ENERI stakeholder conference

The stakeholder conference took place in Athens, September 2017 and brought together 55 different stakeholders from universities, industry, science journalism, ministries as well as project participants from several European projects on research ethics and research integrity. The conference aimed to bring together expertise from various fields and perspectives to discuss central questions as to the current and future state of RE/RI in terms of practices, infrastructures, committee compositions, among other related subjects. The conference also included the WP6 workshop on “what constitutes expertise and qualifications in RE/RI?”²²

The objective of the workshop was to receive stakeholder input on what constitutes expert skills, competences and qualifications within the fields of research ethics and research integrity. These stakeholder input were then to enter into the WP6 empirical programme that aims to explore and establish a set of relevant expert criteria/indicators for the creation of a European e-community/database of international experts (see introduction).

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The workshop was designed in a participatory manner utilizing the World Café format (Slocum, 2003). Stakeholders were divided into four groups with each group discussing a set of five questions related to the following themes: a) skills and competences b) qualifications c) certification d) EU database of RI/RE experts (see questions in table 4.1 below). All groups were to reach consensus on all questions and report their answers in a table format using flip charts. One group representative subsequently presented group findings in the joint plenary session.

In terms of results, all groups were highly engaged in effective and wide-ranging discussions on the subjects pre-determined for debate. While not all groups reached consensus on the best ways to proceed with constructing the database/establishing expert criteria, consensus was reached on what type of key discussions need to be settled in the further phases.

The group discussing the **EU database on RI/RE expert** emphasized the following key points/discussions:

²² This summary also features into a modified summary report from the Athens meeting.

- It is decisive to establish the main objective, with building a database of experts in order to tailor the most appropriate and effective database design – for instance who are the main target groups/end users? It was also suggested to pilot the database in a closed environment to assist with designing the (search) tools. It was also recommended to designate the database as a ‘registry’ instead of a database. The group also raised the important question of how to monitor/register experts and the need to be highly aware of the different implications of different exclusive/inclusive criteria.
- In general, there seems to be consensus that the database should be open and inclusive and adopt a diverse approach to expert criteria that mirrors the complexity of RE/RI “in and around research”.

In terms of key **expert skills and qualifications**, the two groups discussing the matter gave emphasis to the following set of skills/competences/qualifications as important to possess:

- Scientific literacy; awareness/understanding/interest in ethical principles/issues; diversity in backgrounds; assessment skills (benefits, risks, societal challenges); mediation/deliberation/decision-making skills; awareness of societal/cultural differences → education, experience, interpersonal skills

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The group that discussed the pros and cons of **certification** reached agreement on a positive approach towards certification but they put forward that it should be a personal issued certification related to portfolio/CV.

Table 4.1. Workshop questions addressed in the Athens stakeholder meeting

Skills and competences:

- From a collective standpoint (Ethics Units [EUs]) what skills and competences must/should an Ethics Unit have?
- Please prioritize such skills and competences (eg. must have-s/nice to have-s)
- Which competencies and skills do you regard to be the most important in RE/RI assessments on an individual level for any member of the Ethics Units?
- Please group these as hard skills, soft skills, process skills and emotional skills; which do you find especially important?
- Are there any skills all members of Ethics Units should possess while are there skills that only specific members must have?

Qualifications:

- ❖ What kind of formal or informal qualifications must Ethics Unit members possess? (Ethics training; experience in ethics assessment; legal; philosophical; gender; sociology; etc.)
- ❖ Are some of these qualifications more useful than others? (education, experience, emotional skills etc.)
- ❖ Please prioritize skills and qualifications?
- ❖ Are there any qualifications that can be quantified/specified? (eg.: 3 years of research experience; 3 ethics assessment projects; formal training/education)
- ❖ Is there a need for such quantification? Please explain

Certification:

- ☐ Should there be certification applied in assessing qualifications?
- ☐ On which level should these qualifications be applied: process; training offered or personal?
- ☐ Are there any frictions/contradictions between currently employed qualifications?
- ☐ How are these contradictions addressed? How may they be solved?
- ☐ Should there be a central body (EU level) offering such certifications or should any such there be an accreditation process for certificates/certificators?

EU database of RI/RE experts:

- ✓ In order to build an European database of international experts within the field of research ethics and integrity, which types of criteria and qualifications do you think experts need to poses to become a member of the database? (education, experience, teaching, process and emotional skills?)
- ✓ What are “must have” criteria and qualifications?
- ✓ Which criteria and qualifications would be “nice to have”?
- ✓ Would European institutions – including yours – benefit from more standardised practises, processes and qualifications?
- ✓ Should there be any particular research ethics and integrity training programs or upgrading of skills required? (Initial training? Recurring upgrading?)

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4.1.1 Summary of main points– expert study and stakeholder recommendations

The expert study as well as the stakeholder conference point to several key recommendations, discussions and awareness points, which would be beneficial to explore further in the following empirical program and hence in terms of constructing a preliminary set of RE/RI criteria/indicators:

- Data base objectives should be further explored and determined in terms of user needs.
- The issue of database design that occupied the stakeholder workshop compared to the expert interviews, but database access, structure, key features, profile set-up and pre-defined classifications etc. are all topics, which will require further consideration.
- Interview experts and stakeholders highlight many of the same core RE/RI competences and skills but agree to adopt an inclusive, broad and multidisciplinary approach towards RE/RI expertise.
- Stakeholders reached consensus on the issue of certification and agreed to the advantages of issuing a personal certification for expert database membership.

Expert interviewees, in turn, were much more divided in their view on the benefits of certification.

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6. Further information

a) Interview guide - qualitative study of RI/RE expert qualifications

A. Introduction

- Short presentation/recap of interview objectives
- Information about lack of anonymity
- Informed consent
- Information about recording/handling of interview material

B. Background & organisation (2 mins)

1. Could you please tell me in a few sentences how your work is related to research ethics and integrity?
2. Could you also tell me how your institution/organisation/committee/network work with RE/RI? What are your main responsibilities? (e.g. advisory role, decision-making power, legal mandate, review, project coordination, teaching etc.)

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C. RE/RI skills/expertise/qualifications (25 mins)

Our main focus in this interview is on RE/RI expertise, qualifications and certification.

Therefore:

3. Which existing skills and competences do you regard to be the most important in your institution/organisation/committee/network? – Individual qualifications/collective-team competences? (Will you describe these qualifications in detail?)
4. What kind of formal or informal skills and qualifications must members/employees/researchers possess? (Ethics training; experience in ethics assessment; legal; philosophical; gender; sociology; etc.)
5. You have mentioned different types of skills. Could you group these as hard skills (e.g. education), soft skills (e.g. communicative), process skills (e.g. adm./management) and emotional skills (commitment, open minded) that you find especially important?
6. Are some of these skills and qualifications more useful than others? (education, experience, emotional skills etc.) Could you prioritize them?

7. Are there any qualifications that can be quantified/specified? (e.g. 3 years of research experience; 3 ethics assessment projects; formal training/education). Is there a need for such quantification?
8. Are there any frictions/contradictions between currently employed qualifications? If yes: How are these contradictions addressed? Solved?
9. Which competences/qualifications – if any - should be further pursued? And how?

General EU database qualifications:

10. In order to build a European database of international experts within the field of research ethics and integrity, which types of skills and qualifications do you think experts need to pose to become a member of the database? (education, experience, teaching, process and emotional skills?) – within specific scientific disciplines?
11. What do you think are “must have” criteria and qualifications? Why?
12. In addition to those, which criteria and qualifications would be “nice to have”? Why?
13. In your opinion, do you think European institutions – including yours – would benefit from more standardised practises, processes and qualifications - and hence greater harmonisation among countries? Why? (pros and cons?)

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D. Training/certification (10 mins)

In interviewees’ institution:

14. Is there any particular RE/RI training programs or upgrading of skills required in your institution/organisation/committee/network?
 - if yes: Initial training? Recurring upgrading? Which type of training programme is applied?
 - if no: do you think members/employees would benefit from ethics/integrity training? Which type? Why?
15. Should there be also certification applied? On which level: process; training offered or personal?

EU database:

16. Do you believe it should be mandatory to undergo an ethics/integrity training programme to become a member of the European expert database? If yes: do you think completing the expert training programme should result in a personal training certificate?

17. In your opinion, do you think a form of issued personal certification should be required to be a member of the European expert database? (pros and cons?)

E. Other (5 mins)

18. Before we finish – is there anything else you think we need to cover?

B. Email invitation to expert interviewees

Dear,

As part of the EU funded project ENERI (European Network of Research Ethics and Research Integrity <http://eneri.eu/>), the European Commission wishes to build an e-community and database of international experts within the field of research ethics and integrity. Through an empirical research programme, ENERI aims to explore and establish a set of relevant expert criteria/indicators that cover a broad set of key expert skills and qualifications within these fields.

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In your capacity as a renowned expert within the field of research ethics and integrity, we take the liberty to contact you to ask whether you will be able to participate in a short expert interview within the next two weeks?

The interview will take place by phone or skype and last between 30-50 minutes. The interview will focus on your perception of key RI/RE skills and qualifications in terms of your own work within these areas and in regard to the European expert database.

Would you be able to participate? Possibly, you can email me with a preferable time to reach you by phone to set up the interview appointment.

Kind regards,

Tine Ravn, PhD, Assistant Professor

On behalf of

The Institute for Advanced Studies, Vienna; the Danish Centre for Studies in Research and Research Policy, Aarhus University and the ENERI consortium

C List of informants

	Inst. Category/ type of RI/RI involvement	Name	Institution/organisation/network
1.	National REC	Helene Ingierd, Director	The National Committee for Research Ethics in Science and Technology (NENT), Norway
2.	Ethics expert in H2020 Expert associate in the center promotion of science Researcher	Dr. Dubravka Vejnovic	Expert associate in the Center for the Promotion of Science, Belgrade, Serbia Researcher at the institute of human genetics, Faculty of Medicine, University of Belgrade
3.	European network of RECs Permanent Working Party of Research Ethics Committees	Prof. Dr. med. Elmar Doppelfeld	Chair of EUREC Founder of Permanent Working Party of Research Ethics Committees in Germany
4.	Researcher, manager	Prof. Mgr. Ing. Petr Kratochvíl, Ph.D.	Director of the institute of international relations in Prague, Czech Republic
5.	University RIO	Palle Bo Madsen,	Head of The Committee for Responsible Conduct of Research Aarhus University, Denmark
6.	European networks of RIOs National funding organisation	Asael Rouby	Vice-Chair, ENRIO Programme Manager, Legal Adviser, Research Integrity Office, The Luxembourg National Research Fund (FNR)
7.	National funding org.	Maura Hiney	Health Research Board (HRB) Head of Policy, Evaluation and External Relations, Dublin, Ireland

8.	European advisory body of the President of the European Commission	Jim Dratwa	Head of European Group on Ethics in Science and New Technologies
9.	European Association of research managers and administrators (EARMA)	Nik Claesen	Managing director, Belgium
10.	Industrial representative	Anja Gilis	Janssen, Pharmaceutical Companies of Johnson and Johnson, Belgium
11.	RE researcher Research ethics coordinator	Dr. Marjo Rauhala	Unit of Gender Competence Office, Technical University, Vienna, Austria
12.	Journal editor RI researcher	Dr. Ana Marusic	Professor of Anatomy and Chair of the Department of Research in Biomedicine and Health at the University of Split School of Medicine, Split, Croatia Co-editor in Chief of the <i>Journal of Global Health</i> and President of the European Association of Science Editors

D. Informed consent template

European Commission Horizon 2020 Framework Project (H2020), **Project ID:** 710184 - European Network of Research Ethics and Research Integrity (ENERI)

Informed Consent for participation in ENERI Expert Interviews

Project and expert interview objectives

The “European Network of Research Ethics and Research Integrity” (ENERI) broadly wishes to establish an operable platform of actors in the fields of research ethics and research integrity. As part of the project, the European Commission wishes to build an e-community and database of international experts within the field of research ethics and integrity.

Through an empirical research programme, among here a set of expert interviews, ENERI aims to explore and establish a set of relevant expert criteria/indicators that cover a broad set of key RI/RE expert skills and qualifications.

Audiovisual material

Each expert interview will be recorded on an audio device for the purpose of analysis. It will be stored in a safe place at the investigators facilities. Each participant may demand removal of his/her recordings by simple request.

Anonymity

Interviewees participate in their position as experts within their field and will not appear anonymous. However, complete interview transcript will only be accessible to members of the project team and handled with confidentiality.

Delete as necessary

1. Have you been informed about the objective of the interviews? YES/NO
2. Have you had an opportunity to ask questions and discuss this study? YES/NO
3. Do you understand that you are free to withdraw from this study YES/NO
 - at any time? Without giving any reason for withdrawing?
4. Do you agree to take part in this study YES/NO
5. Do you accept the way in which we use your data in line with established data protection guidelines and regulations? YES/NO
6. Do you accept that you participate as an expert and that full anonymity is not possible to grant? YES/NO

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Participant's signature:

Contact's signature:

Name in Block letters:

Day/month/year

Appendix 3. Quantitative survey

RI/RE expert qualifications

Results from a quantitative survey

ENERI, WP6, 6.1

2018

Robert Braun, Magdalena Wicher & Tamara Brandsätter

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1. Summary

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. Work package 6 addresses the main objective in the project “to create an e-community/database (...) of European and whenever relevant international experts in the different fields of research ethics and integrity”, which “should notably ensure the certification of the knowledge level of the experts” The main objectives are (1) to explore and develop indicators that are widely accepted in the heterogeneous field of RE/RI representing expertise in the two areas to be implemented in the expert data base; (2) to evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly; and (3) address the construction, mapping, and monitoring of central expert criteria.

We have created an empirical program to address the above mentioned issues in a systematic way. The first step of the program was an extensive literature review and desktop research, followed by a quantitative research interviewing experts. The next phase of the program is the qualitative survey. This will be followed by a series of consensus conferences to involve potential users of the database as well as lay persons and validate our findings.

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Key takeaways from the quantitative survey:

Skills and competences: Based on the survey we may conclude that respondents value ‘experience’ or praxis in RE/RI assessment the most; while also prioritizing that experts possess some theoretical ethics/philosophy (and to a lesser extent ‘legal’) knowledge to back up their practical experiences. When assessing required skills, respondents say that experts should be personally committed open-minded and impartial people, with analytical minds to solve the ethical/moral dilemmas that may arise as problems, while also being able to convey and deliberate their potentially diverging opinions or point of views.

Use of database: Respondents find an international database/e-community to be a very useful initiative and name various uses from the potential use to ‘find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. and ‘find research ethics experts for European/international networks’.

Database design: Respondents suggest that the design of the database should (pre)define all skills and expertise of the database members as well as years of practical experience and believe these should be somewhat more important than specific educational background. When it comes to specific skills and competences respondents value RE/RI experience as well as previous experience in RE/RI commissions experience the most, closely followed by

scientific/research experience. As for the structure of the database, respondents value a selection of short self-descriptions based on key areas of expertise, rather than tick-off standardized categories or a few standardized themes and blank cells to be filled in with whatever the expert finds important.

Training: The majority of respondents claim that training should only offered on a voluntary basis and not be made mandatory and ‘any ethics/integrity training’ should be accepted as opposed to a certified training by an official body.

Certification: When defining the type of certification required for the training a majority would opt for a certification to be received at the end of the completion of the course as opposed to the requirement of certifying the teaching method of the training.

Proposed questions for the consensus conference series:

- Should a broad, diverse and inclusive or a normative, limited approach to RE/RI expertise be applied? (expert types, RE/RI topics, organisational levels etc.)
- Individual profiles should be highly structured and include a large number of ‘tick-off’ standardised categories or should be semi-structured and only include only a few predefined key areas/themes of expertise + open categories?
- Should the database offer self-registration or members should be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental and institutional bodies?
- Should members go through a training course before being allowed to register in the database?
- Should individual profiles indicate years of experience within particular areas of expertise or experience need not be quantified?
- Should the database require personal certification of any type or such certification is not required?

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2. Introduction

As discussed in our “RI/RE expert qualifications/Results from a qualitative expert interview study (Ravn et al. 2017) research integrity (i.e. professional standards of conducting research) and research ethics (i.e. moral principles embedded in research) are pertinent topics in scientific research. The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. It is the ambition that such a shared platform - comprised of expert networks and groups, ethics and integrity commissions, assessment boards and expert databases etc. - may serve as a tool for promoting awareness and exchanging and disseminating knowledge, as well as substantiating and harmonizing cross-country experiences, standards, guidelines and ‘best practices’ within the fields of research ethics and research integrity.

Specifically, work package 6 (WP6) in ENERI addresses the main objective in the project “to create an e-community/database (...) of European and whenever relevant international experts in the different fields of research ethics and integrity”, which “should notably ensure the certification of the knowledge level of the experts” (ENERI 2016, 40). Following this objective, it is stated that “an essential precondition for setting up and running this database is a meaningful as well as widely accepted definition of criteria that constitute expertise in the fields of research integrity and ethics” (ENERI 2016, 40). The main objectives in this regard are:

- To explore and develop indicators that are widely accepted in the heterogeneous field of RE/RI representing expertise in the two areas to be implemented in the expert data base
- To evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly

Hence, the key tasks of certification of experts and the development of indicators address the construction, mapping, and monitoring of central expert criteria. To explore how such criteria are to be defined and how RE/RI expertise is to be constituted, an initial literature review is conducted with the objective to review, map and assess existing literature, reports and European projects concerning potential expert qualifications/indicators (for the report see Ravn, Braun & Drivdal 2017). As a second step an empirical programme consisting of interviews with selected experts follows the literature review. This is followed by an online survey that targets a variety of actors, stakeholders and organizations. As depicted in figure 1 below, the process of identifying, exploring and conducting expert indicators and criteria

involves an initial stakeholder meeting and ends with a series of consensus conferences, in order to discuss the preliminary set of RE/RI indicators and particular database objectives/design matters.

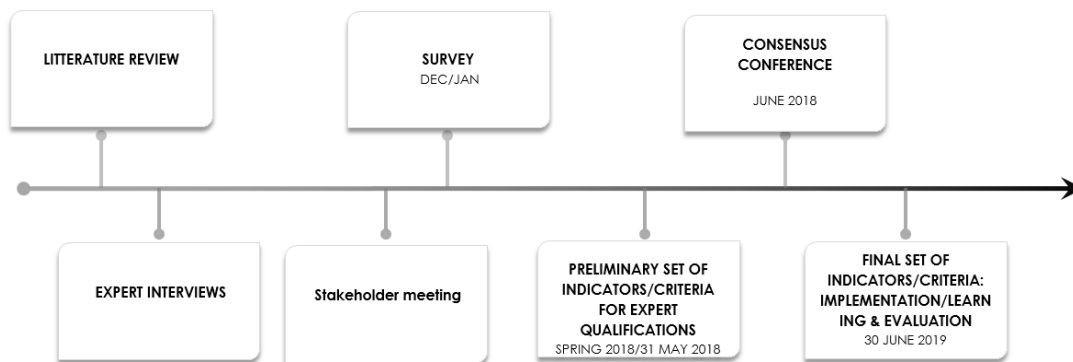


Figure 1. Overview of ENERI, WP6

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The report at hand details the results from online survey that targets a variety of actors, stakeholders and organizations.

3. Methods and approach

The main reasons for opting for an online survey as an addition to the expert interviews are to a) open up the heterogeneous fields of research ethics and research integrity to a variety of actors, b) to inductively explore and generate knowledge on potential RE/RI expert criteria from a variety of key representatives and c) to collect structured information that may complement insights and inform the remaining empirical programme, especially assist in fine tuning the questions to be discussed at the consensus conference series.

The questionnaire starts with a description of the ENERI project with a focus on the e-community/database of European and international experts in the different fields of research ethics and integrity. The questionnaire also describes the rationale of the database as assisting responsible people to set up oversight bodies, committees, teaching and training and other processes involving people with the appropriate skills, competences and experience.

The questionnaire was created in January 2018 and was distributed by the European Network of Research Integrity Offices (ENRIO) network as well as was shared at the EUREC members meeting that took place on 15th of February 2018 in Berlin. The target sample was 100 respondents; after intensive communication and repeated reminders all together 125 respondents have filled in the questionnaire. An online questionnaire tool was used to collect answers; answers were anonymized through the tool.

In selecting respondents we used non-probability sampling as randomization was not possible in order to obtain a representative sample. Following up on the expert interviews and utilizing the core expert networks of RE/RI, ENRIO and EUREC, we used expert sampling as a subset of non-probability sampling.

We contacted and utilized the membership of two main RE/RI organizations with a broad expert base and good geographic distribution:

- European network of RECs (EUREC)
- European network of research integrity offices (ENRIO)

Utilizing these networks even the non-probability sampling strategy allows for a certain amount of variation and geographic and institutional distribution due to the experts' particular experiences and institutional affiliation.

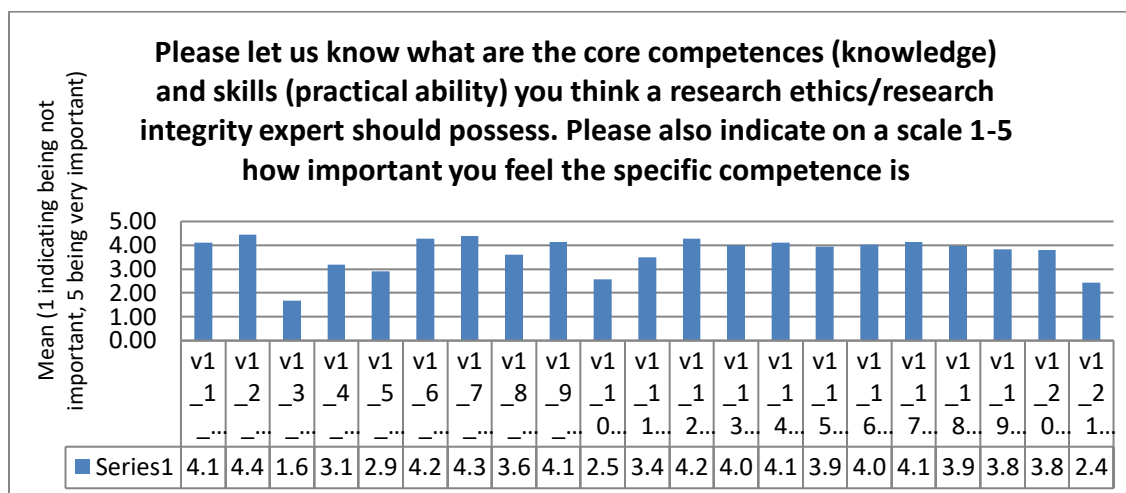
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The following sections will summarize and present the main results of the online questionnaire.

4. Results from the questionnaire

4.1 Competences and skills

The first set of questions aimed at getting an overview of which competences (knowledge) and skills (practical abilities) should experts in the database possess.



Respondents found “research/science” competence the most important (4,45) closely followed by ‘ethics assessment’ (4,27) and ‘integrity assessment’ (4,39) competencies. This confirms our findings in both the literature review and the expert interviews that experts value experience in assessment as the most important competence in being an ‘expert’ in RE/RI. Aside from experience respondents value ‘ethics/philosophy competences’ (4,10) high while ‘legal competences’ (3,18) relatively lower. Respondents seem to value ‘religious competences’ (1,69) as the least important in RE/RI expertise.

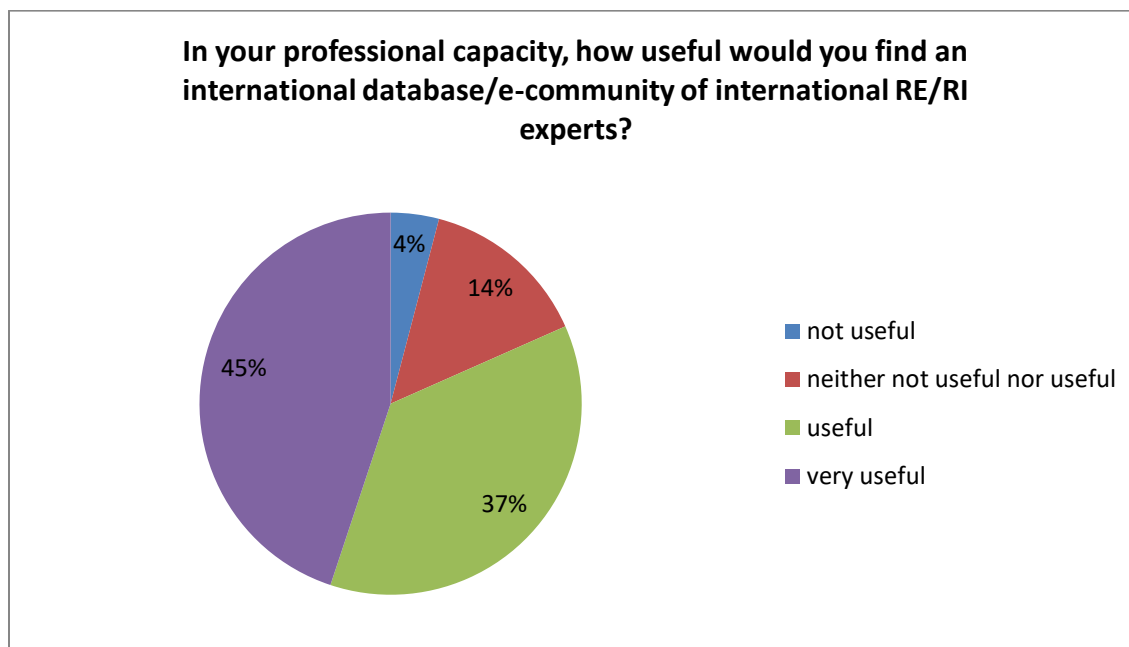
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When assessing required skills of RE/RI expertise ‘impartiality’ (4,29), and ‘open mindedness’ (4,14) are rated as the most important skills, while ‘personal commitment’ (4,14) is also valued. ‘Administrative’ (2,57) and ‘technical’ (2,43) skills are valued the least, while ‘analytical’ (4,10), ‘problem solving’ (4,00) and ‘debate/deliberation’ (4,02) skills are also highly valued.

Key points:

Based on the survey we may conclude that respondents value ‘experience’ or praxis in RE/RI assessment the most; while would like to see experts possess some theoretical ethics/philosophy (and to a lesser extent ‘legal’) knowledge to back up their practical experiences. When assessing required skills respondents say that experts should be personally committed, open-minded and impartial people, with analytical minds to solve the ethical/moral dilemmas that may arise as problems, while also being able to convey and deliberate their potentially diverging opinions or point of views.

4.2 Use of database



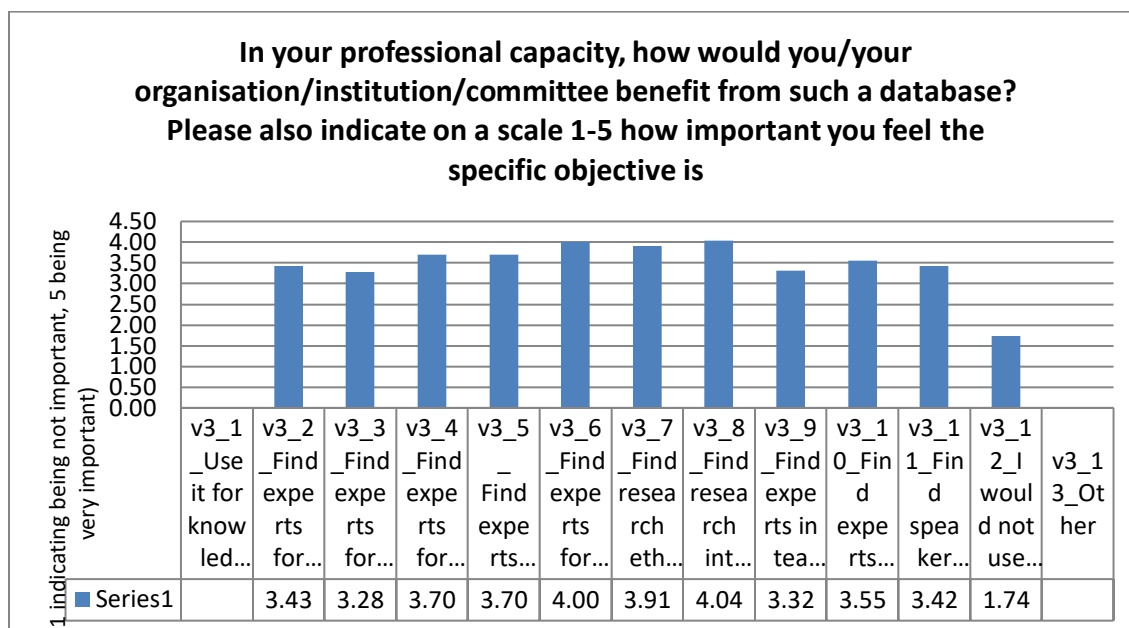
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Respondents find an international database/e-community to be a very useful initiative with 82% answering useful or very useful and only 4% saying that such a database would not be beneficial.

When asking about potential use of such a database/e-community respondents name various uses on an almost equal basis with the potential use to 'find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. (4,00) and 'find research ethics experts for European/international networks' (4,04) somewhat standing out. However respondents would find the database in looking for experts for ethics reviews (3,43), for RE/RI committees (3,28/3,70) or find expert to assist research integrity officers (3,70). Respondents would also use the database to look for experts in teaching RE/RI (3,32/3,55) or to be RE/RI speakers at conferences.

Key points:

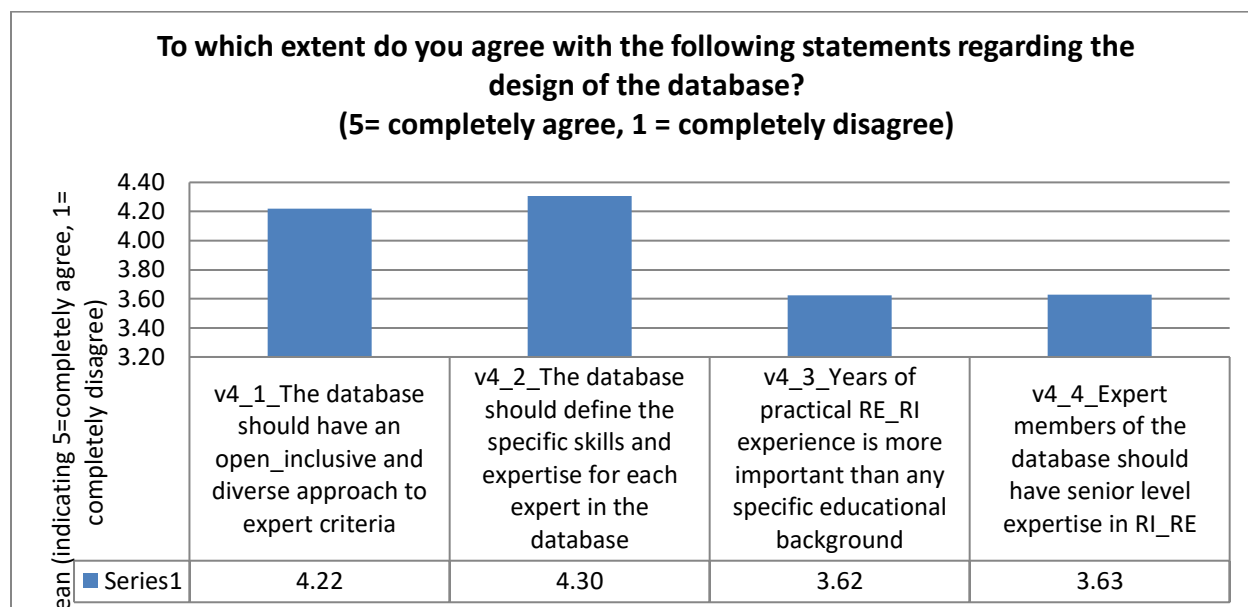
Respondents find an international database/e-community to be a very useful initiative and name various uses from the potential use to 'find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. and 'find research ethics experts for European/international networks'.



4.3 Database design

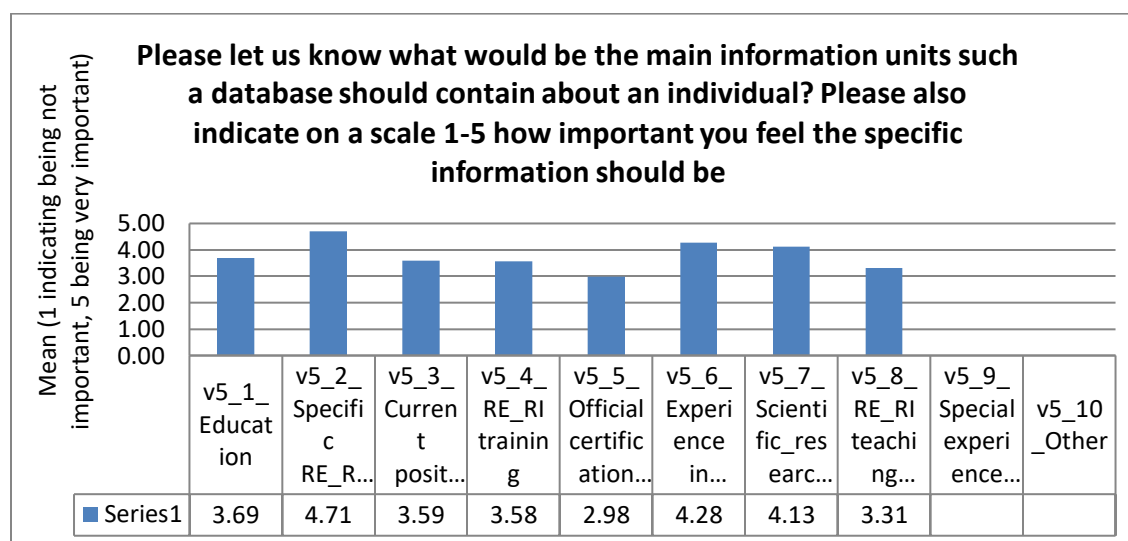
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When discussing database design in light of the different skills and competences respondents suggest that the design of the database should (pre)define all skills and expertise of the database members (4,3), while they value an open and inclusive approach (or co-design) to a somewhat lesser extent (4,22). Respondents also seem to suggest that while the years of practical experience is somewhat more important than specific educational background (3,62), senior level experience is not overly important (3,63).

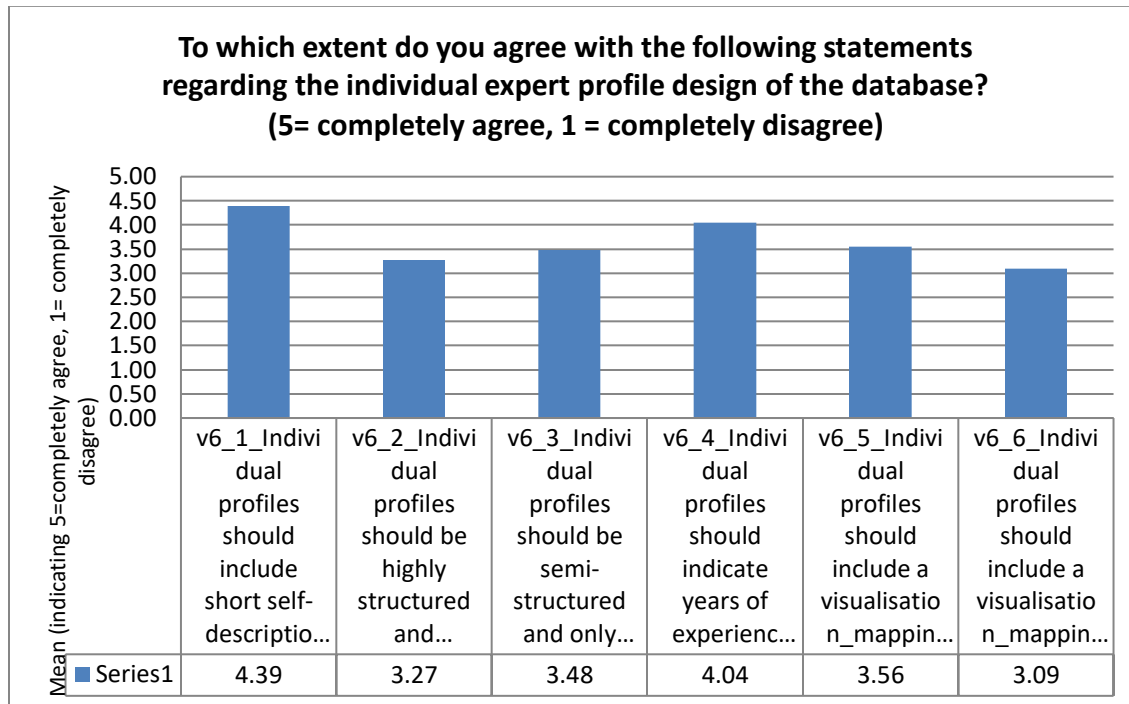


When it comes to specific skills and competences, in accordance with what has been said previously, respondents value RE/RI experience (4,71) as well as previous experience in RE/RI commissions experience (4,28) the most, closely followed by scientific/research experience (4,13). Specific education, current position as RE/RI expert or RE/RI teaching experience are all valued somewhat (3,69/3,58 and 3,31 respectively); while respondents seem to be skeptical towards the importance of an 'official RE/RI certification' system.

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When inquiring about the structure of the database respondents value a number of short self-descriptions of key areas of expertise (4,39) over tick-off standardized categories (3,27) or a few standardized themes and open cells for filling in whatever the expert finds important (3,48); visualization of expertise or skills to acquire seem only mildly important to respondents.



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As for registration of experts in the database respondents seem to be split between an open and a controlled approach to registration; while a relative majority would opt for a more controlled approach (39%). The biggest number of respondents would suggest an EU controlled registration (25%), while some respondents suggest that experts should be nominated by the relevant national bodies (14%). Open access and self-assessment is a clearly minority opinion (12%).

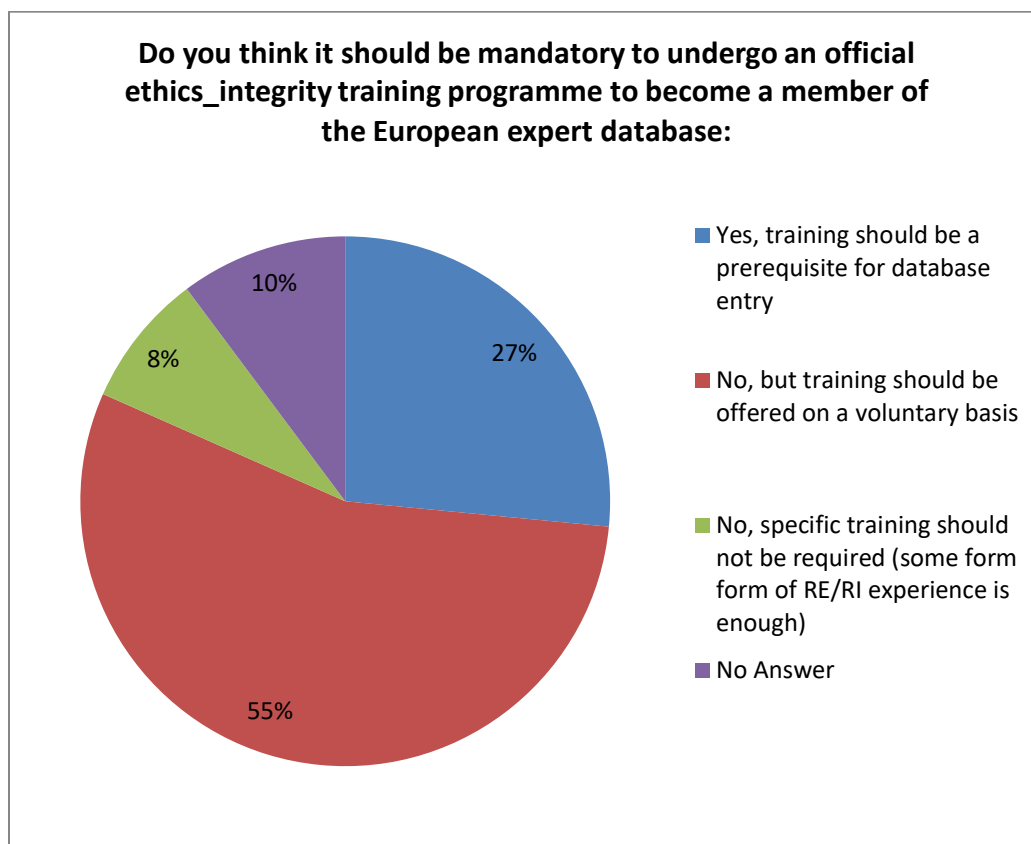


Key points:

Respondents suggest that the design of the database should (pre)define all skills and expertise of the database members as well as years of practical experience is somewhat more important than specific educational background. When it comes to specific skills and competences respondents value RE/RI experience as well as previous experience in RE/RI commissions experience the most, closely followed by scientific/research experience. As for the structure of the database respondents value a number of short self-descriptions of key areas of expertise over tick-off standardized categories or a few standardized themes and open cells for filling in whatever the expert finds important.

4.4 Training requirements

Consistent with previous answers on the importance of ‘official training’ the majority of respondents claim that training should only be offered on a voluntary basis and not be made mandatory (55%). However also slightly more than one quarter of respondents (27%) suggest that subscribing to an official RE/RI training should be a prerequisite to be entered into the database.



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When discussing the kind of training required for database entry/voluntary participation, the relative majority of respondents suggest that ‘any ethics/integrity training’ should be accepted (36,7%) as opposed to a certified training by the database management team or other official body (28,6%). However, almost one quarter of the respondents (24,5%) do not find this issue relevant at all and would accept any solution.

Key points:

The majority of respondents claim that training should only offered on a voluntary basis and not be made mandatory and 'any ethics/integrity training' should be accepted as opposed to a certified training by an official body.

4.5 Certification



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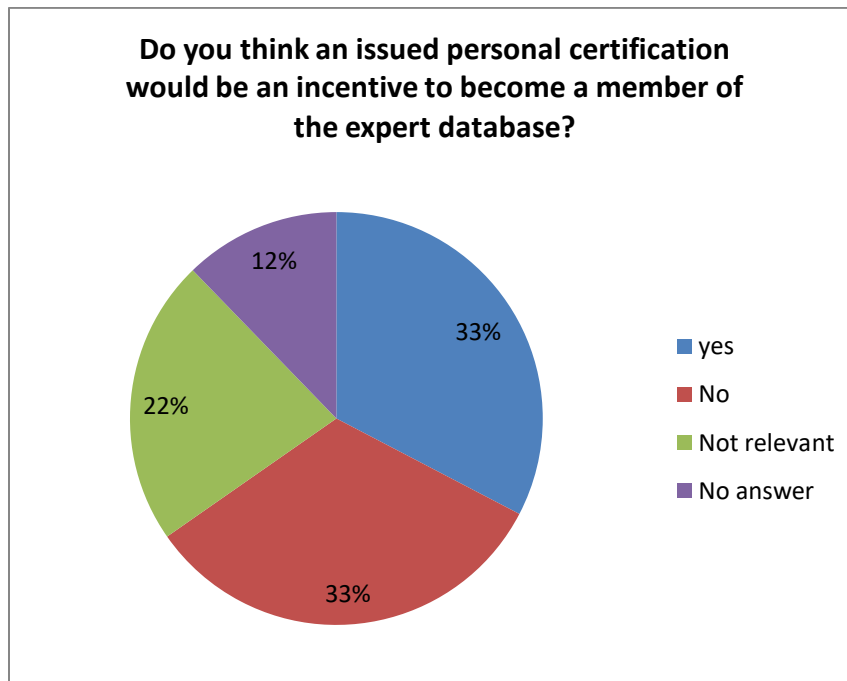
When defining the type of certification required for the training, a majority (53,1%) would opt for a certification to be received at the end of the completion of the course as opposed to the requirement of certifying the teaching method (20,4%) or the whole course having a certification (6,1%).

Respondents are split as to whether some kind of personal certification be issued for members of the database with a somewhat higher proportion of respondents opting for no personal certification (35%) over issuing some form of certification (26%). This is consistent with the next answer, where respondents are evenly split between assuming that such

certification would be an incentive to enter the database (33%) as opposed to those who think that such certification would not provide any incentive (33%).

Key points:

When defining the type of certification required for the training, a majority would opt for a certification to be received at the end of the completion of the course as opposed to the requirement of certifying the teaching method.



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4.6 General remarks

Respondents were also given the opportunity to add their own thoughts. Some reinforced the goal of the project as to establish a European RE/RI database claiming that “my organization would immensely profit from an international database! So my wish is just that it becomes reality...” Most open answers concern the question of certification (again: in accordance with our expert interviews). One respondent refers to the fact that “certification is not available in all EU member states therefore, it should not be a criteria” while another writes that design should focus “at people who have already done work in the field / have hands-on experience, rather than imposing training or certification”.

5. Conclusion

Our expert interviews represented a broad agreement among experts concerning the valuable aspect of establishing a database, adopting an inclusive, diverse and transparent approach to RE/RI expertise. This has been reinforced in the quantitative survey. As for skills and qualifications most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise. According to experts, formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria. These preferences have also been confirmed by the quantitative research as survey respondents value ‘experience’ or praxis in RE/RI assessment the most; additionally they would like to see experts possess some theoretical ethics/philosophy (and to a lesser extent ‘legal’) knowledge to back up their practical experiences. Expert interviews have shown that soft skills need to feature in the individual database profiles and into the final sets of criteria/indicators in some form. Respondents in the quantitative survey have emphasized ‘impartiality’, and ‘open mindedness’ as well as ‘personal commitment’. ‘Administrative’ and ‘technical’ skills are valued the least, while ‘analytical’, ‘problem solving’ and ‘debate/deliberation’ skills are highly valued therefore will potentially be included in the database design. Experts are in agreement with respondents in our survey that an optional training course before entering the database might be relevant, but it should not be mandatory. Experts see a personal certification as a good idea and so do respondents in the survey: a majority would opt for a certification to be received at the end of the completion of an RE/RI training course.

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6. References

ENERI (2016): Proposal template. European Network of Research Ethics and Research Integrity.

Ravn, T. Braun, R. & Drivdal, L. (2017). Review of RI/RE expert qualifications. ENERI, WP6, 6.1., 1- 33.

7. Further information

Questionnaire for online survey about research ethics and -integrity expertise

Prepared by: Robert Braun, Tine Ravn, Erich Griessler, Niels Mejlgaard

Introduction

Research integrity (i.e. professional standards of conducting research) and research ethics (i.e. moral principles embedded in research) are pertinent topics in scientific research. The changing nature of science and of research infrastructures together with a rising number of cases of research misconduct, have shown a continued importance for different kinds of research ethics and research integrity expertise – for instance individually represented by RE/RI practitioners, policy/law experts and academic experts or collectively in the form of RI/RE committees and assessment boards, among others.

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The EU commission wishes to build an e-community/database of European and international experts in the different fields of research ethics and integrity. Such a database would assist responsible people in setting up oversight bodies, committees, teaching and training and other processes involving people with the appropriate skills, competences and experience. We would like to seek your advise on how to best design the expert database, including your assessment on relevant and core RI/RE expert skills and competences.

1. **Please let us know what are the core competences (knowledge) and skills (practical ability) you think a research ethics/research integrity expert should possess. Please also indicate on a scale 1-5 how important you feel the specific competence is (1 -- being not very important; 5 -- being very important).**

- Ethics/philosophy competences [scale 1-5]
- Research/science competences [scale 1-5]
- Religious competences [scale 1-5]
- Legal competences [scale 1-5]
- RE/RI teaching competencies [scale 1-5]
- Ethics assessment/review competencies [scale 1-5]

- Integrity assessment/review competencies [scale 1-5]
- Other (open) [scale 1-5]:

Skills (scroll down menu – you can choose more than one)

- Interpersonal [scale 1-5]
- Open-mindedness [scale 1-5]
- Administrative [scale 1-5]
- Communicational/mediational [scale 1-5]
- Impartial [scale 1-5]
- Problem solving [scale 1-5]
- Analytical [scale 1-5]
- Decision-making [scale 1-5]
- Debate/deliberation [scale 1-5]
- Personal commitment [scale 1-5]
- Co-operation [scale 1-5]
- Societal/cultural awareness [scale 1-5]
- Assessment (benefits, risks, societal challenges) [scale 1-5]
- Technical/IT [scale 1-5]
- Other (open) [scale 1-5]:

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2. **In your professional capacity, how useful would you find an international database/e-community of international RE/RI experts? (1 -- being not very useful; 5 -- being very useful)**
3. **In your professional capacity, how would you/your organisation/institution/committee benefit from such a database? Please also indicate on a scale 1-5 how important you feel the specific objective is (1 -- being not very important; 5 -- being very important).**

Objectives (scroll down menu – you can choose more than one)

- Use it for knowledge exchange/mutual learning among experts [scale 1-5]
- Find experts for ethics reviews [scale 1-5]
- Find experts for research ethics committees (RECs) [scale 1-5]
- Find experts for research integrity committees [scale 1-5]
- Find experts to assist research integrity officers (RIOs) [scale 1-5]

- Find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. [scale 1-5]
- Find research ethics experts for European/international networks [scale 1-5]
- Find research integrity experts for European/international networks [scale 1-5]
- Find experts in teaching research ethics [scale 1-5]
- Find experts in teaching research integrity [scale 1-5]

Other (open) [scale 1-5]:

- I would not use such a database

4. To which extent do you agree with the following statements regarding the design of the database?

	Completely agree	Partly agree	Neither agree nor disagree	Partly disagree	Completely disagree
The database should have an open, inclusive and diverse approach to expert criteria					
The database should define the specific skills and expertise for each expert in the database					
Years of practical RE/RI experience is more important than any specific educational background					
Expert members of the database should have senior expertise					

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5. Please let us know what would be the main information units such a database should contain about an individual? Please also indicate on a scale 1-5 how important you feel the specific information should be (1 -- being the not important; 5 -- being very important)

- Education [scale 1-5]
- Specific RE/RI expertise [scale 1-5]
- Current position at employing institution [scale 1-5]
- Ethics/integrity training [scale 1-5]
- Certification [scale 1-5]
- Experience in ethics/integrity commissions [scale 1-5]
- Scientific/research experience [scale 1-5]
- RE/RI teaching experience
- Special experience [scale 1-5] – please specify _____
- Other [scale 1-5]:

6. To which extent do you agree with the following statements regarding the individual expert profile design of the database?

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	Completely agree	Partly agree	Neither agree nor disagree	Partly disagree	Completely disagree
Individual profiles should include short self-descriptions of key areas of expertise					
Individual profiles should be highly structured and include a large number of 'tick-off' standardised categories					
Individual profiles should be semi-structured and only include few predefined key areas/themes of					

expertise + open categories					
Individual profiles should indicate years of experience within particular areas of expertise					
Individual profiles should include a visualisation/mapping of key competencies/skills					
Individual profiles should include a visualisation/mapping of potential capacities for skill development					

7. How are experts to register into the database?

- It should be based on open access and self-assessment
- Registry of members should be managed and monitored by a relevant EU management team
- Experts should be nominated by relevant national governmental and institutional bodies
- Other, please specify: _____

The next questions concern possible training requirements to get into the expert database:

8. Do you think it should be mandatory to undergo an 'official' ethics/integrity training programme to become a member of the European expert database?

- Yes, training should be a prerequisite for database entry
- No, but training should be offered on a voluntary basis
- No, specific training should not be required (some form of experience is enough)

9. **If training is required do you think that only certified ethics/integrity training should be accepted?**
 - a. Yes, only certified trainings should be accepted
 - b. No, any ethics/integrity training should be accepted
 - c. Not relevant
10. **If certification of ethics training is required, do you think the certification should be based on:**
 - a. The process/method applied
 - b. The full training must have a certification
 - c. The individual should receive a certification on completion

The next questions concern the issue of expertise certification:

11. **Do you think that a personal certification should be issued and required as a member of the expert database?**
 - a. Yes
 - b. No
 - c. Not relevant
12. **Do you think an issued personal certification would be an incentive to become a member of the expert database?**
 - a. Yes
 - b. No
 - c. Not relevant
13. **If you have any further comments regarding relevant research ethics/research integrity skills and qualifications, please state them below.**

14. If you have any further recommendations on how to design the expert database, please state them below

Thank you very much for answering the questionnaire!

On behalf of The Institute for Advanced Studies, Vienna; the Danish Centre for Studies in Research and Research Policy, Aarhus University and the ENERI consortium

Appendix 4. Consensus conferences.

Deliverable report for

ENERI

Grant Agreement 710184

Deliverable 1.3

Summary of consensus conferences

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Due date of deliverable:

Actual submission date:

ENERI identifier	ENERI_Deliverable_1_3.docx
Editor	Robert Braun, Institute for Advanced Studies
Authors	Robert Braun, Institute for Advanced Studies Elisabeth Frankus, Institute for Advanced Studies Julia Schmid, Institute for Advanced Studies Erich Griessler, Institute for Advanced Studies
Work Package / Task	WP1 / Task 1.3
Document Status	Final 1
Dissemination level	PU
	* PU – Public; PP - Restricted to other programme participants (including the Commission Services); RE - Restricted to a group specified by the consortium (including the Commission Services); CO - Confidential, only for members of the consortium (including the Commission Services).

Document History

Version	Date	Reason of change
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0.1	29.08.2018	Draft 01
1.0	29.11.2018	Final version

1. Description of Task at the GA

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity.

2. Objectives and needs of the deliverable

In work package 1 (WP1: Coordination and management) the Midterm Consensus Conference aims to be a platform of exchange with stakeholders; the aim is to get the community involved that is interested in RE and RI. In work package 6 (WP6: Monitoring and Certification) main objectives are (1) to explore and develop indicators that are widely accepted in the heterogeneous field of research ethics (RE) and research integrity (RI) representing expertise in the two areas to be implemented in the expert data base; (2) to evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly; and (3) address the construction, mapping, and monitoring of central expert criteria. An empirical program has been developed. The first step of the program was (a) an extensive literature review and desktop research followed by (b) a quantitative survey interviewing experts. This was followed by (c) a qualitative survey. This was complemented by a series of (d) consensus conferences to involve in the key decisions about the database potential users as well as non-experts to validate our findings.

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3. Conclusions

The consensus conferences mainly supported the view of the experts. Potential users and other key stakeholders come to a conclusion (with strong minority opinions in the case of Aarhus regarding Q1 and Q3) that:

- *Q1: A broad, diverse and inclusive approach should be applied to RE/RI expertise;*

- *Q2: Individual profiles should be semi-structured; they are to include predefined key areas/themes of expertise to be filled in with short descriptions + open categories;*
- *Q3: The database should offer self-registration of experts;*
- *Q4: Members must not go through a training course before being allowed to register in the database, but such cours(es) should be offered as optional;*
- *Q5: Individual profiles should not focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAUs participated in) within particular areas of expertise (majority position only);*
- *Q6: The database should not require personal certification of any type to enter the database.*

4. Deviations from DoA

As opposed to one major Consensus Conference (for which the planned funds were not appropriate) we opted to run a series of consensus conferences in four European cities (Aarhus, Athens, Vienna, Vilnius), assisted by our local ENERI partner institutions, inviting mostly local stakeholders. This gave us the chance to (1) reach out to a wide network of stakeholders; (2) get a good geographic distribution across Europe; (3) acquire comparative information across the different venues and stakeholders. The deviation was approved.

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5. Next steps

Based on the results of the empirical program and the consensus conference series the database design will be fine-tuned to fit findings; also once the database will be up and running in pilot phase WP6 will develop and carry out an evaluation and learning program “to evaluate and adapt the validity of indicators and the usability of the registration process”. This will be carried out by an online questionnaire and a series of interviews with experts and stakeholders (Task 6.3).

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1. Summary of the first phase of the empirical program

The ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. Work package 6 (Monitoring and Certification) addresses the main objective in the project “to create an e-community/database (...) of European and whenever relevant international experts in the different fields of research ethics and integrity”, which “should notably ensure the certification of the knowledge level of the experts” The main objectives are (1) to explore and develop indicators that are widely accepted in the heterogeneous field of research ethics and integrity representing expertise in the two areas to be implemented in the expert data base; (2) to evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly; and (3) address the construction, mapping, and monitoring of central expert criteria.

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An empirical program has been developed by the contributors to WP 6 (Aarhus University and the Institute for Advanced Studies in Vienna) to address the above mentioned issues in a systematic way. The first step of the program was (a) an extensive literature review and desktop research²³ followed by (b) a quantitative survey interviewing experts²⁴. This was followed by (c) a qualitative survey²⁵. This was complemented by a series of (d) consensus conferences to involve in the key decisions about the database potential users as well as non-experts to validate our findings. This report contains the results of the consensus conferences.

²³ Cf. Robert Braun et al. ENERI Deliverable 6.1.: Summary of empirical programme and preliminary set of indicators for e-database, submitted 30.05.2018. Appendix 1, pp. 15-44.

²⁴ Cf. Robert Braun et al. ENERI Deliverable 6.1.: Summary of empirical programme and preliminary set of indicators for e-database, submitted 30.05.2018. Appendix 2, pp. 45-73.

²⁵ Cf. Robert Braun et al. ENERI Deliverable 6.1.: Summary of empirical programme and preliminary set of indicators for e-database, submitted 30.05.2018. Appendix 3, pp. 74-90.

Based on the series of empirical investigations (a-c) a set of preliminary indicators were developed²⁶. The preliminary set of indicators were as follows:

Database as a whole:

- Both interview experts and experts in the quantitative survey find an international database/e-community to be a very useful initiative and name various uses from the potential to ‘find experts for guidance on RE/RI policies, guidelines, codes of conduct’ etc. and to ‘find research ethics experts for European/international networks’.
- There is a broad agreement among experts to adopt an inclusive, diverse and transparent approach to RE/RI expertise.

Database design:

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- The database should
 - (pre)define all skills and expertise of the database members (but some level of co-design is accepted);
 - contain short self-descriptions (focusing on evidence based experience) on key areas of expertise rather than tick-off standardized categories.

Database registration:

- It is advised to use a controlled (supervised and managed) approach either by an EU institution controlled registration or nomination of experts by relevant national bodies (as opposed to an open registration process based on self-registration).

²⁶ Cf. Robert Braun et al. ENERI Deliverable 6.1.: Summary of empirical programme and preliminary set of indicators for e-database, submitted 30.05.2018. pp. 9-11.

Database indicator(s):

DI1: Inclusivity

DI2: Diversity

DI3: Transparency

DI4: Definition of skills and expertise

DI5: Description of experience

Skills and qualifications:

- Experience in ethics assessment processes (as expressed in number of years; membership in EAUs; etc.) is valued generally by experts over qualification;
- From a qualifications point of view experts are to possess:
 - Theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences;
 - Experience in
 - Scientific/research skills
 - Ethical commitment and awareness
 - Critical thinking
 - Assessment and review
 - Experience in
 - Interpersonal communication/debate

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Expertise indicator(s):

EI1: Quantifiable experience in EAUs or assessment processes

EI2: Ethics/Philosophy knowledge

EI3: Specific and relevant experience in scientific research

El4: Peer offered experience in critical thinking, ethical commitment

Training:

- Training should be offered on a voluntary basis (especially for those with limited or no EAU experience)
- 'Any accredited ethics/integrity training' (without having defined who would provide such accreditation) should be accepted as opposed to a certified training by an official body.

Training indicator(s):

T11: Training option (mandatory/volunteer)

T12: Provider of training

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Certification:

- Potential for
 - personal certification for expert database membership
 - personal certification for participation in training course offered

Certification indicator(s):

CI1: Certification of database membership

CI2: Certification of training participation

2. The Consensus conferences

The preliminary indicators were tested, discussed and fine-tuned in a series of consensus conferences. The consensus conference (CC) design was to follow traditional CC methodology (Einsiedel and Eastlick 2000, Joss 1998, P. Nielsen et al. 2006) to fit purpose. The long, resource intensive consensus conference design – involving meeting and deliberation for several successive weekends – was shortened to a one day session. Stakeholders received information about the subject matter of the CC one week before the CC.

One day consensus conferences have been used to reach expert consensus in medical research (Grudzen et al. 2016). The consensus conference format applied attempts to reach a middle ground between a ‘lay persons’ and ‘expert participation’ consensus conference and invited a varied group of people who are not experts in RE/RI but are/may be stakeholders relevant to RE/RI processes. The goal was to reach consensus among invited stakeholders in required qualifications and certifications for EU level RE/RI expert database. The required consensus was limited to questions posed.

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2.1. Methodology

The rationale for the consensus conferences were based (a) on the critique of a technocratic treatment of (technology related) policy issues (Tribe 1972, Lakoff 1977, Laird 1993) as well as the growing concern that citizens and non-expert users have a stake (Freeman 1994) in the outcome of RE/RI and may thus have important views and insights to contribute. We have been clear to participants that their opinion(s) would have a real influence over possible outcomes of database design. On the other hand the consensus seeking was limited to the issues discussed and distilled through the empirical research program and the deliberation was not opened to the whole issue of RE/RI or the relevance and appropriateness of the European RE/RI database as such.

The consensus conferences took part in four European cities (Aarhus, Athens, Vienna and Vilnius) during the month of June, 2018. Local ENERI teams assisted in the preparation (venue, invitations, catering) and stakeholder selection.

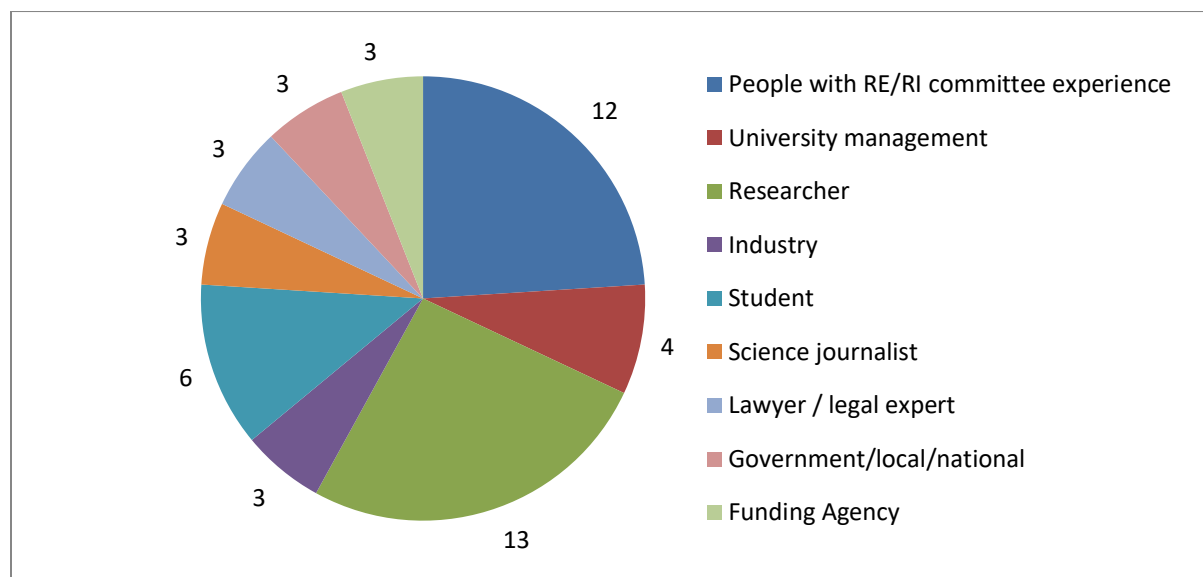
Consensus conferences were designed by IHS (Robert Braun & Elisabeth Frankus), were facilitated by Elisabeth Frankus. Robert Braun gave a brief introduction to the consensus conferences and the ENERI project as well as briefly presented the findings of the empirical programme. Robert Braun also acted as expert in both being an 'expert' in the research done so far (thus representing the information and opinion of 'experts' harvested) and as an academic (having had formal education/PhD in philosophy and research/teaching experience in philosophy/ethics) as well as an 'expert' on RE/RI in more general terms.

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12-15 stakeholders in each venue were selected from the following potential future database "user" groups:

- People with RE/RI committee experience
- University management
- Funding agency
- Researchers
- Students
- Industry people
- Science journalist
- Lawyer/legal expert
- Government/local/national

Altogether 50 stakeholders participated in the four cities. The distribution of stakeholders in the four consensus conferences were as follows:



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In accordance with Laird (1993) "substantial education" was involved about the project, RE/RI and controversies as well as the preliminary findings. Participants received in advance a report on the findings of the empirical program – literature review; expert interviews; stakeholder workshop input; expert survey (approx. 15 pages) as well they were presented with a power point presentation summarizing key findings and process at the beginning of each CC.

All participants signed an informed consent sheet. (cf. Appendix III. 7.5.)

In each of the consensus conferences six questions were posed focusing on:

- on structure and particular design of individual expert profiles;

- on format of registration of experts;
- on formal and relevant education, RE/RI experience;
- on optional training course;
- on personal certification.

In each of the consensus conferences these questions were asked from the participants:

- *Should a broad, diverse and inclusive or a predetermined, limited approach (defined by an authoritative entity, including the ENERI project) to RE/RI expertise be applied? (expert types, RE/RI topics, organisational levels etc.)²⁷*
- *Individual profiles should be highly structured and include a large number of 'tick-off' standardised categories or should be semi-structured; include predefined key areas/themes of expertise to be filled in with short descriptions + open categories?*
- *Should the database offer self-registration or members should be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental and institutional bodies?*
- *Should members go through a training course before being allowed to register in the database?*
- *Should individual profiles focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAUs participated in) within particular areas of expertise or experience need not be quantified?²⁸*

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²⁷ The question was altered for more clarity and better reflection on originally intended content (After 2nd event).

²⁸ Question was altered for more clarity and better reflection on originally intended content (after 1st event).

- *Should the database require personal certification of any type or such certification is not required?*

Each consensus conference followed a similar format. After the introduction (event, project, purpose, main findings to date) participants received the list of questions with a brief explanation of their relevance in the project as well as potential answers/points of decisions and the position of experts (as surveyed in the interviews and quantitative analysis). After some time for reading through, participants discussed the questions in pairs and in a plenary format to arrive at a shared understanding. The expert (Robert Braun) had been available to clarify questions and also inform participants about the opinion of experts regarding the questions. Before deliberation the purpose and aim of the expert database was presented and discussed by participants.

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After arriving at a shared understanding of the questions participants selected a 'Chairperson' to moderate the World Café as well as the consensus making from within the group. Chairpersons were also asked to moderate the plenary when consensus was not reached. Chairpersons also took part in the debate to avoid creating a hierarchy. In all CCs Chairpersons applied on a voluntary basis and were accepted by the participants. For the role and function of the Chairperson see Appendix 6.

This was followed by a World Café discussion (Brown and Isaacs 2005) on three tables and in two sessions (3 questions in each of the two rounds) with one participant acting as rapporteur for each table. Thus all participants (with the exception of the rapporteurs in each session) had the chance to discuss all questions. After the deliberation rapporteurs presented the consensus (if arrived at) or presented diverging opinions and arguments. After table presentations non-consensus questions were discussed and final consensus was achieved in a plenary session. During all phases of deliberation the expert (Robert Braun) was available for clarification; supporting expert opinion

in matters related to the question discussed or clarifying the opinion of experts). A reflection round closed the consensus conference in which participants could express their opinions regarding the process, the method and the results achieved.

At all stages – introduction, question clarification, World Café and reflections – participants could express their opinions freely and reflect on anything they found appropriate. However, during the sessions attention was called to the fact that the aim of the CC is to arrive at a consensus in the questions posed to complement the empirical program of the project.

After the session, based on a detailed photo protocol and specific notes taken, a consensus sheet and an ‘impact or consensus statement’ (Beighton 2017) was created that summarized the questions, remarks, issues discussed and the consensual answers arrived at as well as the consensus in a narrative format, respectively (see appendix X). These sheets, together with a reflection form, were sent out for final approval/remark/comments to participants. Participants were instructed to comment only if they found that certain answers/consensus were misinterpreted or mistakenly reported. No further personal comment or opinion was expected from the participants.

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2.2. Consensus

The following table summarizes the consensus arrived in the series of consensus conferences.

	Vienna	Athens	Aarhus	Vilnius	Consensus
Question 1: Should a broad, diverse and inclusive or a normative, limited approach to RE/RI expertise be applied?	C: Open approach to be applied, with a strong element of normative limiting standards provided by an	C: Open approach to be applied, with a clear definition of who and how can amend the database structure and definition of	B: Normative Approach [Set criteria to be applied]	A: Open Approach [Broad, diverse, inclusive]	Open approach to be applied [Minority position/ Aarhus: Normative Approach]

(expert types, RE/RI topics, organisational levels etc.)	authoritative source	'minimal standards'			
Question 2: Individual profiles should be highly structured and include a large number of 'tick-off' standardised categories or should be semi-structured; include predefined key areas of expertise to be filled in with short descriptions + open categories?	B: Semi structured, self descriptive + open categories	B: Semi structured, self descriptive + open categories	B: Semi structured, self descriptive + open categories	B: Semi structured, self descriptive + open categories	Semi structured, self descriptive + open categories
Question 3: Should the database offer self-registration or members should be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental	A: Self-registration of experts	A: Self-registration of experts	C: Managed by relevant EU team with national [non] governmental bodies nominating	D: Self-registration of experts combined with technical human verification of data for appropriateness	Self-registration of experts [Minority position/ Aarhus: Managed by relevant EU team with national [non] governmental bodies

I and institutional bodies?					
Question 4: Should members go through a training course before being allowed to register in the database?	B: Training course should be offered but made optional	B: Training course should be offered but made optional	B: Training course should be offered but made optional	B: Training course should be offered but made optional	Training course should be offered but made optional

<p>Question 5: Should individual profiles focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAU's participated in) within particular areas of expertise or experience need not be quantified?</p>	<p>A: Expertise should be quantified where applicable in specific field</p>	<p>B: Expertise should NOT be quantified</p>	<p>C: individual profiles should contain quantifiable and quality measures as well</p>	<p>B: Expertise should NOT be quantified</p>	<p>Majority: Expertise should NOT be quantified</p> <p>Minority: quantifiable and quality measures as well</p>
<p>Question 6: Should the database require personal certification of any type or such certification is not required?</p>	<p>B: Personal certification is NOT required to enter the database</p>	<p>B: Personal certification is NOT required to enter the database</p>	<p>B: Personal certification is NOT required to enter the database</p>	<p>B: Personal certification is NOT required to enter the database</p>	<p>Personal certification is NOT required to enter the database</p>

The consensus conferences mainly supported the view of the experts. Potential users and other key stakeholders come to a conclusion (with strong minority opinions in the case of Aarhus regarding Q1 and Q3) that:

- *Q1: A broad, diverse and inclusive approach should be applied to RE/RI expertise;*
- *Q2: Individual profiles should be semi-structured; they are to include predefined key areas/themes of expertise to be filled in with short descriptions + open categories;*
- *Q3: The database should offer self-registration of experts;*
- *Q4: Members must not go through a training course before being allowed to register in the database, but such course(s) should be offered as optional;*
- *Q5: Individual profiles should not focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAU's participated in) within particular areas of expertise (majority position only);*
- *Q6: The database should not require personal certification of any type to enter the database.*

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In a few cases there was a strong divergence from the majority position [Q1; Q3: Aarhus] and in case of Q5 opinions were diverging and no consensus among the four locations can be established. In all consensus meetings strong and useful remarks were added to the main consensus that may be used well when designing the database.

Based on the CCs potential users and other key stakeholders suggest a broad, diverse and inclusive approach to database membership. As for database structure participants suggest a semi-structured approach comprising of predefined key areas of expertise to be filled in with short descriptions, complemented with open categories to add specific skills and experience. Participants of the CCs opted for self-registration of experts (with some potential minimum experience requirements). They also suggest that the platform should offer optional training course(s) in ethics as well as other skills. Participants suggest that experience should not be quantified eg. by the number of years, cases dealt with etc, however a strong minority opinion emerged that some quality measures should also be applied to inform users about the specifics of the experience that has been quantified. It emerged that personal certification should not be applied as an entry criteria.

2.3. Remarks

Besides the consensus achieved in the four CCs, several additional remarks were noted in the different events.

Definition of expertise: Some stakeholders suggest that further to our research expertise should be defined and set by a select committee and finalized with stakeholders, possibly in a consensus conference.

Diversity: Stakeholders expressed the need for a diversity sensitive approach in database membership, being vigilant to issues of gender, field of expertise, age etc. Participants also noted that national, cultural differences and appropriate representation of all EU countries in the database are to be taken into account. Stakeholders also expressed that ‘lay experts’ [people with willingness to contribute to ethics assessment but no field-specific experience] and ‘NGO/CSO representatives’ should also be included into the database.

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Participants expressed the need for ‘code of conduct’ or some ‘ethical principles’/‘procedural requirements’ to be followed by all ‘experts’ that would define database use and noted that extensive use of online training tools is of essence.

Participants suggest a ‘collective expertise’ element to be added to the database offering users a way to select full EAUs with an element of guarantee that this set of experts will provide a diverse collective set of expertise as opposed to individual expertise.

Stakeholders also suggest that regular updates in input data should be requested by database members; and a global board of experts should report on input data quality and usefulness to supervise consistency and excellence.

2.4. Caveats

Participants in one consensus conference expressed criticism over the unified European database design as a way to offer ethics expertise in research ethics and research integrity. In this consensus

conference participants also found the design of the database, as originating from and by expert members of EUREC and ENRIO as restrictive and top-down. They also found that the consensus conference restricted to the questions posed limited their ability to express their opinion about the subject matter in full.

One participant in another consensus conference expressed a view whether asking specific questions based on expert input about database setup is appropriate without allowing participants to question the legitimacy of the project of creating a community of research ethics and integrity as a whole.

3. Self-reflection

After all CCs we have asked participants to fill in a questionnaire of reflection (see 9.3.) and the organizers have also filled in observation protocols to evaluate the method and the process.

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- **Participants:** recruitment of participants was difficult in all 4 cities. Possible reasons: timing – June is a very busy month (shortly before summer break); the concept, process and rationale of CC was not communicated and explained well enough in the invitation letter – hence participants did not understand their role in the CC. It was also unclear whether (a) as potential ‘users’ participants needed to be ‘experts’ or have some advanced knowledge of RE/RI; (b) participants were ‘private individuals’ or did represent some institutional position (university, student body etc.); (c) participated on a voluntary basis or were ‘sent’ by an institution that received the invitation.
- **Role of ‘expert’ moderator** (Robert Braun): It was not communicated clearly that the role of the ‘expert moderator’ was to (a) represent the ‘experts’ as evidenced in the previous empirical research; (b) to assist in clarifying issues for a non RE/RI expert participant group, therefore in some CCs participants took the moderator’s view/argumentation as personal (biased) opinion and emotions as well as resistance appeared.

- **Cultural differences:** Local/cultural differences were not appropriately taken into consideration and addressed as part of the methodology: regarding participants (selection, type of involvement, depth of involvement, understanding of their influence, discussion format/way how to express ones opinion, punctuality, body language, national incentive schemes – how do participants benefit from the CC? some kind of compensation? €€ etc.), venue (facilities, accessibility, organization, responsibilities, etc.)
- **Participant feedback:** Sending participants results and ask for their feedback did not work well. Potential reasons: time of the year (Summer); additional unpaid work expected; no clear incentives to offer feedback.
- **Deliberation process:** We underestimated how exhausting the deliberation process is for participants, therefore in some of the CCs ‘deliberation fatigue’ was witnessed. As for the format and method, four instead of six questions to deliberate would probably be more appropriate.

4. Database design and preliminary set of database indicators

4.1. Overview and technical translation

Database as a whole:

- There is a broad agreement to adopt an inclusive, diverse and transparent approach to RE/RI expertise.
 - *Technical translation:* the database should NOT only contain names but also clear categories of the types of expertise and experience the specific expert can offer. Database may contain a list of names with some guidance to users as to the specifics of the expertise (RE/RI/General Ethics/RRI etc. in form of a pictogram or acronym)

Database design:

- Database should
 - (pre)define skills and expertise of the database members (but some level of co-design is accepted);
 - *Technical translation:* Database should contain predefined categories:
 - Formal education in philosophy, ethics or law
 - Tercial education (institution, level of degree, title – eg. Oxford University, MA, Philosophy and Ethics)
 - Other formal education (institution, qualification, level) – eg. Training Company, Traning in ethics, Advanced level)
 - Contain short self-descriptions (focusing on evidence based experience) on key areas of expertise.
 - *Technical translation*
 - Tickbox categories [Y/N] with brief self description (max. 50 word ea.)
 - Ethical competences (description to focus on experience)
 - Integrity competences (description to focus on experience)
 - Research/science experience (description to focus on experience)

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- Legal competences (description to focus on experience in EAUs)
 - Ethics assessment/review experience (description to focus on experience)
 - Integrity assessment/review experience (description to focus on experience)
- Contain specific categories for ethics experience
 - *Technical translation:* Main category+boxes, like 'work experience' on LinkedIn
 - RE experience
 - Institution (eg: University of Vilnius, EAU)
 - Task: (eg. Ethics evaluation of proposal)
 - Date
 - Reference person
 - RI experience
 - Institution (eg: University of Vilnius, EAU)
 - Task: (eg. Ethics evaluation of proposal)
 - Date
 - Reference person
 - Other ethics experience
 - Institution (eg: University of Vilnius, EAU)
 - Task: (eg. Ethics evaluation of proposal)
 - Date
 - Reference person
- Contain open categories
 - *Technical translation:* a general open category to be filled in as relevant experience to be provided on top of the above; open textual category, max. 250 words and documents for upload if needed
 - Specific & relevant experience in addition to the above mentioned
 - Documents for upload
- Contain options for peer-review & peer-rating (with transparent identification of peers)
 - *Technical translation:* Peer categories (similar to LinkedIn or star rating or other quantifiable format)

- Peer endorsement of specific skills
- Peer recommendation
- Peer evaluation of specific experience (eg. shared EAU experience)

Database registration:

- It is advised to use an open registration process based on self-registration with some technical oversight, code of conduct and regular (annual or biannual) self-overview.
 - *Technical translation:* Database should provide for self-registration
 - For experts:
 - all categories to be filled in
 - alert to update data on a regular basis (annually or biannually)
 - For users:
 - Information to be provided if data is up-to-date
 - Information to be provided if all categories are filled in
 - For database managers:
 - Data should be verified that self description is filled in with proper information [not truth content but appropriateness]
 - Regular checks of data up-to-dateness (eg. If data is not up-dated regularly expert to drop out of database)

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4.2. Preliminary indicators

<i>Database indicator(s):</i>	
DI1: Inclusivity	✓ Experts should be inclusive of all types and experiences in RE/RI and related fields
DI2: Diversity	✓ Experts should be diverse (specific attention to be paid to gender and geographical distribution)
DI3: Transparency	✓ Data should be proper and up-to-date ✓ Data should be mostly predefined ✓ Open categories should be self-explanatory ✓ Documents should be up-loadable
DI4: Definition of skills and expertise	

- ✓ Skills should be tick-boxed and briefly explained

DI5: Description of experience

- ✓ Experience should be non-quantified (eg. no number of years or number of cases options; but short quality descriptions if appropriate)
- ✓ Peer endorsement; evaluation; reflection options provided (star rating; one word rating etc.)

Expertise indicator(s):

EI1: Experience in EAU or assessment processes

✓ Types of experience:

- Assessment
- Evaluation
- Proposal writing (ethics)
- Expert opinion
- Teaching and training provision
- Specific experience in field:

- RE
- RI

○ Specific experience in ethical field

- Medical
- Digital/ICT
- Gender
- Other

EI2: Ethics/Philosophy knowledge

- ✓ Formal tertiary education in philosophy, ethics or law
- ✓ Formal non-academic training in philosophy, ethics or law
- ✓ In case of legal training: specific field eg. Data management, Human subjects etc.

EI3: Specific and relevant experience in scientific research

✓ Quantified research experience

EI4: Peer offered experience in critical thinking, ethical commitment

✓ Peer categories:

- Shared experience (eg. membership in EAU)
- Peer endorsement of soft skills (predefined categories such as):
 - Communication
 - Deliberative
 - Conflict resolution
 - Collaborative

- Administrative
- Emotional intelligence

Training:

- Training should be offered on a voluntary basis.

Training indicator(s):

T11: Training option (mandatory/volunteer)

- ✓ Trainings offered (pointers)
- ✓ Trainings suggested (links)

Certification:

Certification indicator(s):

C11: Certification of database membership

- ✓ No certification as entry criteria

C12: Certification of training participation

- ✓ No certification of (training or database) participation

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5. References

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6. Appendix I. (Impact Statements)

6.1. Impact statement Aarhus

Participants in this consensus conference expressed criticism over the unified European database design as a way to offer ethics expertise in research ethics and research integrity. In this consensus conference participants also found the design of the database, as originating from and by expert members of EUREC and ENRIO as restrictive and top-down.

As for the preliminary indicators, participants of this conference suggest:

- A normative approach to database design and structure, to be design by an authoritative body and verified by a consensus conference of stakeholders;
- the use of a semi structured, self-descriptive approach to information with tick boxes and open categories;
- that registration of experts should be preceded by a nomination of a national non-governmental body and managed by an EU institution;
- that an optional training course should be offered, focusing on reflection;
- expertise should be quantified, but also quality information should be included;
- that personal certification of expertise acquired before from an authoritative source is not required to enter the database, nor should the database membership constitute an certification of ethics expertise.

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Participants in this consensus conference suggest that expertise should be predefined and set by a select committee and finalized with stakeholders, possibly by a consensus conference; predefined expert criteria should be assessed and revised by stakeholders on a regular basis.

Participants expressed the need for a diversity sensitive approach in database membership, being vigilant to issues of gender, field of expertise, age etc.

Participants noted that national, cultural differences are to be taken into account and represented by the national institution nominating experts.

Participants also expressed that 'lay experts' [people with willingness to contribute to ethics assessment but no field-specific experience] and 'NGO/CSO representatives' should also be included into the database.

6.2. Impact statement Athens

Participants in this consensus conference recognized the importance of research ethics (RE) and research integrity (RI) as an emerging field. Participants emphasized the need for a European database of RE/RI experts that is driven by trustworthiness, openness and interdisciplinarity. In this consensus conference participants acknowledged that the database is not a professional society, therefore expertise is to be understood broadly.

As for the preliminary indicators, participants of this conference suggest:

- an open approach of membership entry to be applied, with a clear definition of who and how can amend the database structure and definition of 'minimal standards';
- the use of a semi structured, self-descriptive approach to information with tick boxes and open categories;
- that experts should be self-registered;
- that an optional training course should be offered by the manager of the database (EU body);
- expertise should not be quantified, however minimum quantifiable entry requirements should be set (eg. minimum years of experience with ethics assessment);
- that personal certification of expertise acquired before from an authoritative source is not required to enter the database, nor should the database membership constitute an certification of ethics expertise.

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While participants in this consensus conference suggest an open approach to registration, data input and data structure, they also suggest that safeguards against misuse should be in place. They also suggest that regular updates in input data should be requested by database members; and a global board of experts should report on input data quality and usefulness to supervise consistency and excellence.

Participants acknowledge that designing a 'standard course' in RE/RI is not feasible. They also suggest that potential members sign a 'code of conduct' or 'procedural requirements' to be followed by all members. They also suggest that after certain years of experience in one field of RE/RI cross-fertilization training is advised (and to be offered).

Participants noted that while personal certification is not required a detailed CV and a personal introduction are to be required.

6.3. Impact statement Vienna

Participants in this consensus conference recognized the importance of expertise in research ethics (RE) and research integrity (RI) as well as the need for a European database of RE/RI experts to be invited to participate in Ethics Assessment Units (EAUs) as well as other ethics endeavors (ethics assessments, training, education, advisory etc.). In this consensus conference participants emphasized the need to include non-academics, practitioners and others with ethics experience to such a database.

As for the preliminary indicators, participants of this conference suggest:

- an open approach of membership entry to be applied, with a strong element of normative limiting standards provided by an authoritative source (e.g. an EU body);
- the use of a semi structured, self-descriptive approach to information with tick boxes and open categories;
- that experts should be self-registered;
- that an optional training course should be offered by the manager of the database (EU body);
- expertise should be quantified where applicable in specific field (e.g. years of experience, numbers of cases involved, etc.);
- that personal certification of expertise acquired before from an authoritative source is not required to enter the database.

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While participants in this consensus conference suggest an open approach to registration, data input and data structure, they also propose that the database should be managed (but management should not mean gatekeeping) and quality controlled by a relevant European body.

Participants acknowledge that designing a 'standard course' is problematic, they also would like to see some unity in the awareness (if not knowledge) of the members of the database, with the mandatory signing/acceptance of a 'code of conduct' or some 'ethical principles'/'procedural requirements' to be followed by all 'experts'.

Participants noted that quantified experience may provide both bias towards more experienced/older experts as well as creating a 'culture of expertise' that favors 'numbers' as opposed to quality/depth of experience; participants suggested to create categories of potential use where high numbers in years or in cases may be less relevant.

Participants suggest a 'collective expertise' element to be added to the database offering users a way to select full EAUs with an element of guarantee that this set of experts will provide a diverse collective set of expertise as opposed to individual expertise.

6.4. Impact statement Vilnius

Participants in this consensus conference found the concept of the database useful and to be widely used. They also voiced concerns about good geographical distribution of among EU countries.

As for the preliminary indicators, participants of this conference suggest:

- an open approach of membership entry to be applied;
- the use of a semi structured, self-descriptive approach to information with tick boxes and open categories;
- that experts should be self-registered, combined with a human technical verification of data;
- optional training courses (offline and online) should be offered by the database, coupled with mandatory signing of code of conduct and technical training of database use;
- expertise should not be quantified;
- personal certification of expertise acquired before from an authoritative source is not required to enter the database, nor should the database membership constitute an certification of ethics expertise.

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Participants in this consensus conference suggest that special attention is to be paid to national differences and appropriate representation of all EU countries in the database.

Participants expressed the need for 'code of conduct' that would define database use.

Participants noted that extensive use of online training tools is of essence.

One participant in this conference expressed a view whether asking specific questions based on expert input about database setup is appropriate without allowing participants to question the legitimacy of the project of creating a community of research ethics and integrity as a whole.

7. Appendix II. (Consensus Sheets)

7.1. Consensus sheet Aarhus

Question 1	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should a broad, diverse and inclusive or a normative, limited approach to RE/RI expertise be applied? (expert types, RE/RI topics, organisational levels etc.)	B: Normative Approach [Set criteria to be applied]		Objective and use of database Sorting mechanism in the database required	Expertise should be predefined and set by a select committee and finalized with stakeholders (possibly: consensus conference)	Every few years (tbd) expert criteria should be assessed and revised. Regular updates created by stakeholders in a stakeholder consensus conference.

Question 2	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Individual profiles should be highly structured and include a large number of 'tick-off' standardised categories or should be semi-structured; include predefined key areas/themes of expertise to be filled in with short descriptions + open categories?	B: Semi structured, self descriptive + open categories		Database use Search requirements Types of tasks experts should have Inclusivity and diversity	Tickboxes are not sufficient Structure and search createria	Take into account national and cultural differences What type of work shall specific experts participate in Inclusive and diversity sensitive selection and recruitment

Question 3	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should the database offer self-registration or members should be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental and institutional bodies?	C: Managed by relevant EU team with national [non] governmental bodies nominating		<p>Initial self registration possible but nomination process applied</p> <p>Authority created by institutional support</p> <p>Diversity policies to be applied</p> <p>Category established for laypersons (as experts)</p> <p>NGOs also to be included</p>	<p>Instead of national government a non governmental institutioun should manage the process in each country</p>	<p>Experts should apply to national institution</p> <p>Database to be also managed locally</p> <p>Diversity should be managed also locally</p> <p>NGOs and other stakeholders also to be included</p>

Question 4	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should members go through a training course before being allowed to register in the database?	B: A training course should be offered but made optional		Training course for reflection Diffulty of creating a standardized course	Difficult to create a standardized course for all experts A compulsory course would limit participation	Instead of course a regular conference of experts to be created for learning and sharing Reflection course to be offered

Question 5	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should individual profiles focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAU's participated in) within particular areas of expertise or experience need not be quantified? ²⁹	C: individual profiles should contain quantifiable and quality measures as well		Expertise is based both on quantity (years, no of cases etc.) and quality measures	Formal education, quality of experience also to be added Numbers can't stand alone	

²⁹ Question was altered for more clarity and better reflection on originally intended content.

Question 6	Consensus (or majority opinion if applicable)	Minority opinion if applicab le	Key points of discussion	Justification of position	Remarks
Should the database require personal certification of any type or such certification is not required?	B: Personal certification is NOT required to enter the database		Some form of quality control required	Certification paper does not make a difference	Institutional legitimacy (see: Q1 should offer guarantees.

7.2. Consensus sheet Athens

Question 1	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should a broad, diverse and inclusive or a normative, limited approach to RE/RI expertise be applied? (expert types, RE/RI topics, organisational levels etc.)	C: Open approach to be applied, with a clear definition of who and how can amend the database structure and definition of 'minimal standards'		<p>Ethics is unstructured so normativity can only be limited</p> <p>Set up a body from members of the community to oversee database development</p> <p>Flexibility of criteria</p>	<p>Main aim is to reach 'uniformity'</p> <p>Expertise should be broadly defined</p>	<p>Build trust</p> <p>Code of conduct to be set up for creating trustworthiness</p>

Question 2	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Individual profiles should be highly structured and include a large number of 'tick-off' standardised categories or should be semi-structured; include predefined key areas/themes of expertise to be filled in with short descriptions + open categories?	B: Semi structured, self descriptive + open categories		As RE/RI is interdisciplinary open fields are required Keywords: trustworthiness, openness, misuse, interdisciplinarity	Openness allows for the emergence of new areas in RE/RI Avoid exclusion	Avoid misuse by people who are not experts but through entering the database may seem like one

Question 3	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should the database offer self-registration or members should be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental and institutional bodies?	A: Self-registration of experts		<p>Multidisciplinarity in RE/RI</p> <p>Inclusivity and fuzzyness</p> <p>Reduction of ambiguity</p>	The territory is broad multi-disciplinary and inclusive	<p>Emphasis on levels of ethical decision making</p> <p>Pay attention to different forms and levels of self registration</p> <p>Regular updates to be required</p> <p>Global board of experts (from database) should do regular check-ups (not as entry criteria but as quality control)</p>

Question 4	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should members go through a training course before being allowed to register in the database?	B: A training course should be offered but made optional		Different courses to be offered Feasibility of 'general course' Lifelong learning principle	Unifed common training is impossible to create (field heterogenety Contradictory to force an 'expert' pass a basic course	A database is not a professional society so expertise is understood more broadly Cross-fertilizing trainings to be offered between areas and disciplines within RE/RI

Question 5	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should individual profiles focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAU's participated in) within particular areas of expertise or experience need not be quantified? ³⁰	B: Expertise should NOT be quantified		Freshness of perspective required Avoiding 'numbers bias'	Other profile details (open, descriptive) should describe experience levels	Minimal (entry) requirements of expertise to be set (eg. 3 years minimum)

³⁰ Question was altered for more clarity and better reflection on originally intended content.

Question 6	Consensus (or majority opinion if applicable)	Minority opinion if applicab le	Key points of discussion	Justification of position	Remarks
Should the database require personal certification of any type or such certification is not required?	B: Personal certification is NOT required to enter the database		Detailed CV requirement Potential misuse (especially output certification) Difference in input and output certification	Creating unnecessary bureaucracy Would create credibility ambiguity (who certifies and why) Would exclude valuable knowledge	Letter of motivation/ expression of interest in becoming a member CV as requirement

7.3. Consensus sheet Vienna

Question 1	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should a broad, diverse and inclusive or a normative, limited approach to RE/RI expertise be applied? (expert types, RE/RI topics, organisational levels etc.)	C: Open approach to be applied, with a strong element of normative limiting standards provided by an authoritative source		Exclusion criteria User responsibility Self selection	Open in terms of topics, concepts of knowledge, decision making processes Open to non academics But some set of normative criteria who can be counted as 'expert'	Database should also contain information on personal motivation Red flags for conflicts of interest

Question 2	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Individual profiles should be highly structured and include a large number of 'tick-off' standardised categories or should be semi-structured; include predefined key areas/themes of expertise to be filled in with short descriptions + open categories?	B: Semi structured, self descriptive + open categories		Power offered to members not a certification authority Members can create their 'classification models'	Better captures real competences Builds on more lasting qualities Members can update an amend tickboxes/info	

Question 3	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should the database offer self-registration or members should be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental and institutional bodies?	A: Self-registration of experts	Some level of management by a relevant EU body (and not national)	EU management not act as gatekeeper User feedback very important	Build on trust and peer input	'Management' should not mean setting standardized entry requirements, but some level of ongoing 'quality management' guaranteeing the credibility and seriousness of the database and the data uploaded.

Question 4	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should members go through a training course before being allowed to register in the database?	B: A training course should be offered but made optional		<p>Who would bare the costs?</p> <p>Trainings are of several types</p> <p>Trainings should focus on case studies and not only traditional knowledge transfer</p>	<p>Training is required for shared understanding but as gatekeeping against entry</p> <p>Opportunity to offer diverse trainings not only one authoritative</p>	While stakeholders agreed with experts that designing a 'standard course' is problematic, they also would like to see some unity in the awareness (if not knowledge) of the members of the database, with the mandatory signing/acceptance of a 'code of conduct' or some 'ethical principles'/'procedural requirements' to be followed by all 'experts'

Question 5	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should individual profiles focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAUs participated in) within particular areas of expertise or experience need not be quantified? ³¹	A: Expertise should be quantified where applicable in specific field		<p>Care should be taken against high age/experience bias</p> <p>Quick look and assessment possibility (based on quantifiers)</p> <p>Better comparability of expertise</p> <p>Concern: who would call members with fewer years?</p>		While stakeholders were in consensus of the need for quantification of experience they also agreed with experts that quantified experience may provide both bias towards more experienced/older experts as well as creating a 'culture of expertise' that favors 'numbers' as opposed to quality/depth of experience; stakeholders suggested to create categories of potential use (eg. Lecturing in or advising on RE/RI) where high numbers in years or in cases may be less relevant.

³¹ Question was altered for more clarity and better reflection on originally intended content.

Question 6	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should the database require personal certification of any type or such certification is not required?	B: Personal certification is NOT required to enter the database	Some stakeholders also shared views (as strong minority opinion) that personal certification may assist in offering more credibility to the database (however not set as an entry requirement)	Specific certifications may not be obligatory but be included as assets Need to develop business model for certification	No gatekeeper function	"there needs to be something of a certification" "third party confirmation of info may be needed (eg. peer process)"

Question +	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should a "collective expertise" element be added to the database offering users a way to select full EAU's with an element of guarantee that this set of experts provide a diverse collective set of expertise as opposed to individual expertise?	A: Collective expertise should be an option				While this issue was raised (and organizers found it interesting, especially in light of SATORI EAU findings) the question was not further debated.

7.4. Consensus sheet Vilnius

Question 1	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should a broad, diverse and inclusive or a normative, limited approach to RE/RI expertise be applied? (expert types, RE/RI topics, organisational levels etc.)	A: Open Approach [Broad, diverse, inclusive]		<p>Ethics as unique experience</p> <p>Multidisciplinary teams and knowledge required</p> <p>National differences to be attended to</p>	<p>Key expert criteria should be as broad as possible</p> <p>Criteria should be evaluated regularly</p>	-

Question 2	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Individual profiles should be highly structured and include a large number of 'tick-off' standardised categories or should be semi-structured; include predefined key areas/themes of expertise to be filled in with short descriptions + open categories?	B: Semi structured, self descriptive + open categories		User friendly database Expertise to cover different needs	Less exclusive approach required Self descriptive and open categories to include uploadable documents/research output etc.	Open questions should be sensitive to private data Database design should be attentive how categories affect/impact user choices Open categories should be optional

Question 3	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should the database offer self-registration or members should be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental and institutional bodies?	D: Self-registration of experts combined with technical human verification of data for appropriateness		Data protection issues Sensitive data checks Language requirements and levels	Input data should be verified by a human agent (from a technical appropriateness point of view) to maintain credibility of the database	Country specific issues need to be attended to Experts may also be delegated by national bodies to maintain good geographical distribution

Question 4	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should members go through a training course before being allowed to register in the database?	B: Training course should be offered but made optional	Signing 'code of conduct' and training in technical usability to be mandatory	Online and offline trainings to be offered Not only frontal training options offered Experience based learning also offered	Multidisciplinary and complex area Code of conduct may be required but not one unified training	Make it clear that it does not offer 'general ethics experts' but expertise in specific ethics fields and areas

Question 5	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks
Should individual profiles focus on quantifiable elements of experience (such as years of experience in ethics, or number of cases assessed or number of EAU's participated in) within particular areas of expertise or experience need not be quantified? ³²	B: Expertise should NOT be quantified, field and formal training is enough		How many years is enough (minimal requirements to be set?) Information about experience limited to past 5 years (for up to date knowledge)	Quantifiable information does not provide for quality of expertise	Quality measures beyond field and formal training also included Different expert types may use different quality information

³² Question was altered for more clarity and better reflection on originally intended content.

Question 6	Consensus (or majority opinion if applicable)	Minority opinion if applicab le	Key points of discussion	Justification of position	Remarks
Should the database require personal certification of any type or such certification is not required?	B: Personal certification is NOT required to enter the database		quality control required misuse of database membership to be avoided	No general certification (as training) is possible	Database membership should not be considered as an overall ethics certification

8. Appendix III. (Additional documents)

8.1. Schedule

Time	Title	Process	Who
Morning session			
9:00	Welcome Explaining purpose/setting expectations Round of introductions Selecting a chairperson among stakeholders (who will manage the deliberations)	<ul style="list-style-type: none"> - Explaining what will happen, why and how - Introducing facilitators & experts - (S)electing chairperson [volunteer] 	Robert Braun, Elisabeth Frankus
9:15	Brief overview of ENERI, the goal of the project, of the findings of the empirical program -- PPT presentation	.ppt presentation of the findings to date	Robert Braun
9:45	Q&A and discussion of the input report and challenges	Panel discussion with facilitator(s)	Robert Braun
10:25	Reading of the questions sheet		All stakeholders
10:30	Coffee break		
10:45	Discussion of the questions to be answered/shared understanding Pairs '10 Fours '10 Eights '10	Presentation of questions Chair taking over session Facilitators assist understanding and clarity Discussion with participants to arrive at shared understanding of the questions, what they entail, use of concepts etc.	Robert Braun, Elisabeth Frankus
11:15	Plenary Q&A	Chairperson discussing open questions after previous session focusing only on "shared understanding"	Chairperson
11:25	First round of deliberation in 3 smaller groups (questions) World Café format	Three groups for three questions (1 ENERI team member in each group observing)	All stakeholders
12.15	Lunch		
Afternoon session			
13:00	Second round of deliberation in 3 smaller groups (questions) World Café format	Four groups for four questions (1 ENERI team member in each group, answering questions if needed, but not moderating)	All stakeholders
14:00	Plenary discussion of results Chaired by selected chairperson	Groups get together, rapporteur present findings, discussion topics, consensual and non-consensual issues	All stakeholders
15:30	Preparing the report/fine-tuning response sheet Two groups (1-3; 3-6 questions)	Stakeholders write up consensus (majority & minority positions) on prepared flipcharts/template for the questions	All stakeholders

Time	Title	Process	Who
16:15	Final round of completing the response sheet Chairman to facilitate	Final write-up	
16:45	Closing remarks/quick round of reflection	Stakeholder reflection & thank you	Robert Braun
17:00	End of day		

Consensus feedback sheet

8.2. Feedback sheet

NAME OF PARTICIPANT:.....

QUESTION	ADDITIONAL POINTS OF DISCUSSION	ADDITIONAL REMARKS	ADDITIONAL JUSTIFICATION
1			
2			
3			
4			
5			
6			

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8.3. Reflection sheet

Reflection topic	Key remarks	Evaluation 1-10 (1 best; 10 worse)
Design and management of the consensus conference <i>[was the CC designed and managed in a way that its main purpose could be achieved]</i>		
Relevance of topic/questions <i>[were the topics/questions important and potentially impactful]</i>		
Diversity of stakeholders and opinions <i>[did the participants represent a wide variety of potential opinions to be found in society, was anytype of person missing]</i>		
Openness of discussion <i>[Did everyone have a voice, was there enough opportunity for all to express opinions]</i>		
Inclusivity of the process <i>[Was the language of the discussion accessible for all; was the setup inviting for participation in the discussion]</i>		
Reflexivity offered <i>[Was the awareness of our limitations of knowledge adequately represented through the design]</i>		

Personal benefit in the process <i>[Did you as participant also gain something of value]</i>		
General evaluation (including food and venue) <i>[Was the setup, the moderation, the atmosphere, the environment appropriate and satisfying]</i>		

8.4. Role-guide to the Chairperson

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A Chairperson is selected among the participants to assist the process of arriving at a consensus in the questions posed at the Consensus Conference. The Chairperson's main task is to assist structuring the conversation, especially in the World Café sessions and the Word Café Planary towards a manageable consensus and the collection of arguments (for and against a potential consensus) as well the main points of discussions and remarks.

The Chairperson participates and engages in the debates and does not (have to) stay neutral.

Roles in the different sessions:

11:15	Plenary Q&A	Chairperson discussing open questions after previous session (pairs/fours/eights) focusing only on "shared understanding"	Role: moderating session
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Guiding questions:

- Did you all arrive at a shared understanding of the terms, of the alternative answers, of the process?
- Is there any clarification needed about language, purpose (goals of the database) or potential outcome (consensus) and how our input will be used?

11:25	First round of deliberation in 3 smaller groups (questions) World Café format	Three groups for three questions (1 ENERI team member in each group observing)	Role: participating in debate
13:00	Second round of deliberation in 3 smaller groups (questions) World Café format	Four groups for four questions (1 ENERI team member in each group, answering questions if needed, but not moderating)	Role: participating in debate
14:00	Plenary discussion of results Chaired by selected chairperson	Groups get together, rapporteur present findings, discussion topics, consensual and non-consensual issues	Role: Moderating discussion/clarifying flipcharts

Discussion format (on flipchart)

Main points of discussion (problems, questions, issues):

Arguments in favor of answer A:

Arguments in favor of answer B:

Arguments in favor of answer C (if applicable):

Remarks and comments:

15:30	Preparing the report/fine-tuning response sheet Two groups (1-3; 3-6 questions)	Stakeholders write up consensus (majority & minority positions) on prepared flipcharts/template for the questions	Role :
16:15	Final round of completing the response sheet Chairman to facilitate	Final write-up	

Final report format:

Example only w/made up answers

Question 1	Consensus (or majority opinion if applicable)	Minority opinion if applicable	Key points of discussion	Justification of position	Remarks

Should a broad, diverse and inclusive or a normative, limited approach to RE/RI expertise be applied? (expert types, RE/RI topics, organisational levels etc.)	C: Open approach to be applied, a national authority, preferably a ministry supervising the process	-	Exclusion criteria EU vs. National Official status	Open in terms of topics, concepts of knowledge Only academics should participate Strong normative criteria who can be counted as 'expert'	Database should also contain information on personal motivation Red flags for failed projects
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8.5. Informed Consent ENERI – Consensus Conference

This informed consent sheet explains the further processing of your data and information provided in the research process and documents your rights.

Description of the Project

The EU funded ENERI project (European Network of Research Ethics and Research Integrity) – a project co-managed by the TSST Research Group at IHS led by Erich Griessler – aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. Project's main objective is "to create an e-community/database (...) of European and whenever relevant international experts in the different fields of research ethics and integrity", which "should notably ensure the certification of the knowledge level of the experts".

Kind of Data collected

During this ENERI Consensus Conference personal data will be collected. This may include your name, age, gender, occupation, professional background, education and your personal opinion. Furthermore pictures and videos will or might be taken.

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Processing and Storing of your Data

For the analysis of the ENERI Consensus Conference minutes will be taken. Your data will be stored in a safe and lockable place at the investigators facility. Only the ENERI research team will have access to this data. At the end of the project your personal data will be erased. In case a publication is not finished by this date the data may be used until the work is finalized. Processed data might survive the project as it may become part of publications and other dissemination activities.

In the ENERI Consensus Conference you will state personal opinions. Full anonymization cannot be granted. Therefore you have the explicit right to not answer a specific question.

Your data will not be sent to third parties. The sole purpose of storing your data is for research. Your data will not be sent to countries outside the European Union.

Data Breach

In case of a data breach the Ethics and Data Protection Manager will be informed by the responsible researcher. Together they will undertake all steps necessary to minimize negative consequences. You will receive a notification about the nature of the Data Breach, the information lost and the actions taken as soon as possible.

Supervision

Questions related to Data Protection can also be directly addressed to tambrino@eurecnet.eu. She will gladly answer all your questions on Data Protection and the Ethics Code applied in the ENERI project.

Your rights

During the ENERI Consensus Conference you are always free to not answer a specific question or leave without any consequences. If you would like to address a question or an issue, please feel free to do so. Furthermore you shall have the right to access, to rectify, to erase, to restrict the processing, the right to data portability and the right to object, as granted in GDPR Article 15-22. You can also withdraw the consent given by signing this form at any time according to GDPR Article 6(1) and Article 9(2) without any consequences. Upon request your local supervisory authority will provide you information on exercising your right according to Article 57(e) GDPR.

Usage of your Data

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The data generated within this ENERI Consensus Conference will only be used for the activities relating to ENERI. This includes the processing for research purposes and dissemination activities. Your data will under no circumstances be sold to any third party.

Dissemination of Results

The data generated will be used for research purposes and dissemination.

After having stated these general conditions and rules, we are looking forward to a good cooperation and positive project results. We would like to thank you in advance for your participation in the project.

The undersigned declare that they understand and consent to the conditions and rules stated in this document. Both parties receive a copy of this declaration of consent.

I _____ (name of the participant) hereby release ENERI and any of its associated or affiliated institutions, their directors, officers, agents, employees and customers from all claims of every kind on account of such use.

Participant's signature:

Contact's signature:

Location, day/month/year

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8.6. Input information for the Consensus Conference series

Results from a qualitative & quantitative study

ENERI

2018

Robert Braun, Tine Ravn³³

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The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 710184.



³³ Other contributors to the research include: Laura Drivnal, Magdalena Wicher, Tamara Brandstatter, Helmut Honigmayer, Marlene Altenhofer

The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 710184.



9. Introduction

As described in the invitation letter you have received the [ENERI](#) (European Network of Research Ethics and Research Integrity) research project aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. The main objective in the project is *“to create an e-community/database (...) of European and whenever relevant international experts in the different fields of research ethics and integrity”, which “should notably ensure the certification of the knowledge level of the experts”*.

We have created a research program to address the above mentioned issues in a systematic way. The next phase of the program is a series of discussions called “consensus conferences” (in 4 European cities: Vienna, Athens, Aarhus and Vilnius) **to discuss and debate with potential “users” of the database the key questions of the database and also validate our findings.**

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In order for participants in the consensus conferences to be able to express their opinions in an informed way, and also to get background information on the current status of research ethics and research integrity in Europe, you would like to share with you our research finding to date.

First of all, in this document we mean *research ethics* to mean the moral principles embedded in research and *research integrity* to be about the professional standards of conducting research.

In the following pages, you will:

- Read about some major ethical scandals in research;
- The current state of research ethics/integrity and the institutions that deal with ethics/integrity;
- What research ethics/integrity experts tell us in interviews about how a database of experts should be built;

- What a wide range of experts tell us in a quantitative online survey about how a database of experts should be built.

After having read this document you are encouraged to form your own opinion about the issues raised therein. Please also prepare some questions, to be answered by experts in the workshop, that would assist you in better understanding the subject at hand and also to enter into debate with others.

We hope you will enjoy reading the document and also participating in the discussions at the workshop.

10. The 10 Biggest Research Scandals in Academic History³⁴

Despite their ostensible intelligence, academics are not at all immune to engaging in risky behaviors that erupt in spectacular displays of controversy. Even if they ultimately prove innocent or unaccountable, their situations always pose inevitable questions about the ethics and legalities behind the research and publication process. The following incidents in particular managed to spark fireworks on an epic scale, inciting a flurry of insight into what needs to be done to better prevent any potentially damaging abuses.

1. Stephen Ambrose (discipline: History):

This popular historian and professor enjoyed bestseller status and mainstream recognition for his inquiries into World War II, most notably *The Wild Blue*, and biographies of presidents Eisenhower and Nixon. By 2002, however, it came to light that Stephen Ambrose quite shamelessly plagiarized much of his research from lesser-known contemporary Thomas Childers, the author of *Wings of Morning*. *Forbes* launched a painstaking investigation into his oeuvre and unearthed entire passages lifted from other historians with no attribution whatsoever — in at least six books and his [doctoral thesis](#), no less! Just as scandalously, the interviews compiled into his allegedly solicited biography of Eisenhower proved to be complete phonies as well.

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2. James Crick, Francis Watson, and Rosalind Franklin (field: Molecular Biology):

Both James Crick and Francis Watson scored themselves some sweet, sweet Nobel Prize lovin' for discovering the double helix structure of DNA. Missing from the honors? Rosalind Franklin, whose research and X-Ray photographs proved integral to the groundbreaking find. The snub remains one of the most prominent controversies regarding the invisible role women played (and, occasionally, still play) in the sciences. While Watson and Crick cannot be said to have plagiarized since they built everything on top of her foundation, the scandal comes in their failure to properly acknowledge her contributions.

³⁴From (adapted): <http://www.onlinecollegecourses.com/2012/06/03/the-10-biggest-research-scandals-in-academic-history/>
Accessed: 17.04.2018.

3. Jan Hendrik Schon (field: Nanotechnology):

Bell Labs physicist Jan Hendrick Schon enjoyed a brief stint as the darling of all things nanotechnological — specifically, transistors — and the journals *Science* and *Nature* scrambled to publish his findings as quickly as he could write them. His fellow scientists, however, noted completely different results when replicating the experiments, with many of them openly questioning how exactly he came to his conclusions. Seeing as how this article isn't about honest folks doing honest things (for the most part, anyways), what came next won't shock anyone except for those with the absolute worst reading comprehension skills. When Schon's employers and Stanford University set about confirming his findings, they found many of his notes missing or deleted, and his machinery too damaged to use. University of Konstanz stripped him of his Ph.D., the journals in question ripped out his offending articles, and the scientific community whipped itself up into a frothing mess arguing over peer reviews and accountability.

4. The Stanford Prison Experiment (discipline: Psychology):

The results may have proven both original and verifiable, but the infamous Stanford Prison experiment blew up over major ethical concerns. Psychology professor Philip Zimbardo set up volunteers in a jail simulation, assigning them roles as either prisoners or guards. Without interfering, he planned to study the dynamics of power abuse and submission/domination scenarios. And study he did, although the students assigned to the unregulated prison guard positions began displaying some distressingly aggressive behavior, going so far as to delight in beating their cowering classmates. Critics expressed understandable worry over what sort of psychological damage the environment and policy of non-intervention might instigate. However, in 1971, the American Psychological Association did grant Zimbardo permission to carry it out.

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5. Ward Churchill (discipline: Philosophy):

Mentioning former University of Colorado at Boulder ethnic studies professor Ward Churchill in certain settings raises tempers, whether directed at the school who fired him or the man himself. In January 2005, Churchill's work attracted controversy because of the circulation of a 2001 essay, "On the Justice of Roosting Chickens", in which he argued the September 11 attacks were a natural and unavoidable consequence of unlawful US foreign policy over the latter half of the 20th century; the essay is well known for Churchill's use of the phrase "little Eichmanns" to describe the "technocratic corps" working in the World Trade Center. Churchill was fired on July 24, 2007, leading to a claim by some scholars that he was fired because of the "Little Eichmanns" comment. Churchill filed a lawsuit against the University of Colorado

for unlawful termination of employment. In April 2009 a Denver jury found that Churchill was wrongly fired, awarding him \$1 in damages. In July 2009, however, a District Court judge vacated the monetary award and declined Churchill's request to order his reinstatement. In September 10, 2012, the Colorado Supreme Court upheld the lower courts' decisions in favor of the University of Colorado. On April 1, 2013, the United States Supreme Court declined to hear the case.

6. Duke University cancer research (discipline: Medicine):

Even after Jan Hendrik Schon inspired fiery discussions about peer editing academic research, Duke University's scandalously falsified reports of a possible cancer cure managed to slip through and raise the serious issue all over again. Although he did not work alone, Dr. Anil Potti serves as the "face" of the potentially life-threatening controversy. His team published findings regarding predicting the spread of lung cancer cells in *The New England Journal of Medicine*, drawing excited gasps from healthcare professionals pondering the possibilities. But when MD Anderson Cancer Center researchers started testing and asking questions, the potentially earth-shattering article crumbled. Confirmation regarding their alleged manipulated results and stolen theories led to looks into Potti and academic partner Joseph Nevins' credentials, and it came out that the former lied about a Rhodes Scholarship. Unsurprisingly, Potti resigned from his position at Duke in 2010.

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7. Nancy Olivieri (discipline: Medicine):

Kids with serious blood disorders such as thalassemia traveled from all over the world to the Hospital for Sick Children in Toronto. There, hematologist Nancy Olivieri tested some new drugs underneath the sponsorship of pharmaceutical giant Apotex, hoping to find cures for their painful conditions. This meant stacks and stacks and stacks of papers governing confidentiality while she conducted her research, and scandal bubbled to the surface when she defied the paperwork and published findings revealing some nasty side effects in the patients who trusted her. Both the Hospital for Sick Children and University of Toronto joined Apotex in chastising Olivieri for breaking her contract, but she still expressed concern with *The New England Journal of Medicine*, ethics boards, and the Canadian government. Her boldness issued forth some challenges regarding what should really come first: contracts or the safety of patients?

8. Diederik Stapel (discipline: Psychology):

For well over a decade, Diederik Stapel of University of Groningen, University of Amsterdam, and University of Tilburg printed up more than a dozen psychological studies, which landed him success in both academic journals and mainstream news outlets. His 2011 suspension happened as a direct result of pretty much all of it being straight-up garbage. More than 30 publishing outfits found themselves duped by falsified research, plagiarism, and all other fun, grossly unethical good times. Although they maintain their anonymity for perfectly understandable reasons, it's suspected that his notoriously abused graduate students – and maybe even a colleague or two – finally went and told the school what was up. Stapel currently contends with criminal charges filed by University of Tilburg for compromising the academic success of everyone who relied on his research.

9. Marc Hauser (discipline: Psychology):

Funny enough, this Harvard psychology professor specialized in cognition and morality. And then he wound up resigning in 2011 after a staggering eight counts of scientific misconduct. Both the National Science Foundation and the U.S. Office of Research Integrity went after him following accusations of falsified and incomplete data regarding his work with tamarins, much of which appeared in the journal *Cognition*. Back in 1995, Hauser's reputation already flickered in and out because of manipulated claims regarding monkey behavior as far back as 1995, but it wasn't until 2010 when he really had to start answering for his ethical violations.

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10. Henrietta Lacks case (discipline: Biology/Medicine):

When Johns Hopkins Hospital harvested Henrietta Lacks' cervical cancer cells in 1951, no laws existed governing the ethics of using (or profiting off) them in medical research without the person's consent — and especially not for an impoverished African-American woman. Journalist Rebecca Skloot's inquiry into the history of how these perpetually-replicating biological marvels led to the creation of the polio vaccine and other earth-shattering scientific breakthroughs, *The Immortal Life of Henrietta Lacks*, renewed interest in the humanity behind the healthcare; in particular, questions regarding why so many made money from HeLa cells while her survivors remained in economic despair. It's a complex, intricate situation to navigate, to be certain, and one whose scandal never fully coagulated until more than half a century later.

11. Ethics and integrity in research

Since the latter part of the twentieth century, developments within science and technology have progressed apace: global R&D investments in research have enlarged significantly; the number of researchers worldwide has increased by millions, within the last decades, and scholars are increasingly working within international and interdisciplinary research fields. Moreover, scientific advances related to emerging technologies, for instance within the field of biotechnology, have brought forth significant and substantial improvements but, in chorus, they have also raised new risks and ethical questions concerning the implications for the human and non-human subjects involved. Several theorists in the 21st century refer to the science-society co-productive nature of scientific knowledge and a corresponding obligation for inclusive and democratic governance. However, one could equally argue that both technological and social innovations demand amplified attention to both research ethics (i.e. moral principles embedded in research) and research integrity (i.e. professional standards of conducting research) or, taken together, efforts to foster responsible conduct of research.

The issue of research ethics and integrity has always been immersed in research processes. Nonetheless, the changing nature of science and of research infrastructures (i.e. funding structures, performance measures, journals, administration etc.) together with a rising number of cases of research misconduct, have resulted in a steady increase in the production of knowledge within this field. Researchers show a growing interest to understand the causes and effects of research misconduct and questionable research practices and to conceptualise and clarify the diverse terminology related to responsible conducts of research. Even so, such efforts have primarily pertained to the biomedical and behavioural sciences and great diversity still exist in the knowledge on performing responsible research across scientific fields. Similarly, while efforts to promote responsible research have resulted in global statements such as the ‘Singapore Statement of Research Integrity’³⁵, a production of codes of conducts and a variety of international and national bodies to assess, oversee and reinforce responsible research practices, cross-country heterogeneity still characterise practices, legislation, guidelines and procedures to enhance ethics and integrity within research. Such heterogeneity also portray efforts to handle and manage allegations of irresponsible research, and no transnational ‘harmonised procedures’ exist.

Several mechanisms, standards and actions are already implemented to further substantiate and foster research ethics and integrity, but as documented in the emerging literature within this field, further measures are required to address and mitigate irresponsible conduct in research. In

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³⁵ www.singaporestatement.org/statement.html

addition to individual, institutional and national measures to safeguard and stimulate such professional standards, transnational efforts to increase and harmonise standards are seen to benefit from professional community and network building and from knowledge exchange and the formation of knowledge bases, among other mechanisms. One way to promote such exchanges is through the setting-up of experts groups and networks whose expertise and qualified membership may add to a greater awareness, dissemination, substantiation and harmonisation of cross-country knowledge, standards and 'best practices' within the fields of research ethics and research integrity.

12. Background information on research ethics and research integrity

Complete consistency in terminology and definitions within the field of research ethics and integrity does not exist in the literature. Nonetheless, the growing body of work within these fields and, consequently, the work performed to understand and conceptualise (ir-)responsible conduct of research increasingly seem to add to a more collective and coherent nomenclature. While research ethics and research integrity often are treated as distinct research fields, they combine general ethical reflections, ethics and law as academic disciplines addressing research activities, moral attitudes of researchers, normative policies of stakeholders and various other ethical expectations. In this review, we adopt the concept of responsible conduct of research as an overall framework that encompasses both the notion of research ethics and research integrity.

A definition of Responsible Conduct of Research (RCR) covers:

‘Conducting research in ways that fulfil the professional responsibilities of researchers, as defined by their professional organizations, the institutions for which they work and, when relevant, the government and public’ (Steneck 2006, 55).

Within this terminology, research integrity is defined as *‘research behaviour viewed from the perspective of professional standards’* and research ethics as *‘research behaviour viewed from the perspective of moral principles’* (Steneck 2006, 56). Research integrity comes from the Latin word *integer* and refers to the aspect of wholeness or completeness and, as encompassed within the Singapore statement, relate to the *‘trustworthiness of research’*. Integrity refers to research findings and the process, in which they are produced (i.e. data, methods, interpretation and presentation/reporting) and whether such processes and findings meet established and appropriate scientific, legal and professional standards.

By comparison, research ethics pertains to the moral issues that occur in the research design and its implementation, for instance in relation to the protection of humans, animals, environment, data as well as the proper protection of other objects.

Responsible conduct of research represents ideal research behavior from the part of individuals and institutions. Opposite, scientific misconduct constitute the worst kind of research behavior and, despite definitional variation, it covers the common understanding of incorporating fabrication (data/case invention), falsification (data/results/process/equipment manipulation), and plagiarism (copying of ideas/data/results/words without crediting).

Responses to allegations of irresponsible research behavior differ from country to country; in some countries, national funding agencies such as the German DGF Ombudsman may act as an alternative reporting/mediator mechanism. In other countries, national bodies may function as advisory bodies only or have institutional oversight or sanctioning responsibilities. Nonetheless, in most countries the concerned university or research institution has the main responsibility for handling allegations of scientific misconduct and quality of research procedures (IAP 2012, 4).

Research Ethics Committees (RECs)

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Research Ethics Committees (RECs) or Ethics Assessment Units (EAUs) are key drivers for promoting ethics in research and in assessing the ethical impacts of research, emerging technologies and innovation projects. Likewise, Research Integrity Offices (RIOs) and committees play a decisive role in promoting and upholding research integrity in their capacity of advising/instructing in current guidelines/regulations and in handling cases of scientific misconduct and questionable research practices.

Research integrity committees at the national level

While RECs seem to be more established bodies internationally, cross-country systems for approaching research integrity appear more heterogeneous. According to a comparison of RI systems for handling scientific misconduct in 15 different countries, three distinct roles can be identified: a) commissions can be tasked with an advisory role b) they can have decision-making power in specific cases or c) have the mandate to ‘supervise institutional processes’.

For nationally established research integrity commissions, a few general characteristics of member composition can be identified:

- Members are appointed for a specific period of time, often between 2-4 years
- Members represents different research disciplines
- Members are highly acknowledged scholars
- Many national commissions have a legal expert appointed (often a judge),
- Some commissions can draw on international experts in specific cases (Danish Agency for Science and Higher Education 2015, 87)

Research integrity committees at the institutional level

Research integrity committees and offices are increasingly being established at universities and research institutions worldwide, and procedures, strategy plans and guidelines have been produced to handle allegations of irresponsible research practices and/or advise on questions related to research integrity and ethics. As mentioned above, their composition and responsibilities may vary significantly among countries and institutions.

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In the US, policies and procedures regarding misconduct in research are most often handled administratively by Research Integrity Offices or more specifically by Research Integrity Officers (RIO). The role of the RIO is not well-defined within a regulatory framework, but it often entails significant responsibilities and the functioning of being both *‘prosecutor, judge, mediator, counsellor, teacher and regulatory manager’*. As to the collective and individual competences of RIO’s, Wright & Schneider emphasizes that *‘the RIO needs personal staff gifted in handling people and, ideally, staff with some training in forensics. Legal counsel, academic subject matters experts, IT experts, and a representative of institutional police or security are also key team members’*.

Research Ethics Committees

Most countries have established research ethics committees to review and monitor research projects, and in particular within the biomedical field of research. In the UK, around 100 research ethics committees are established as independent bodies of the Health Research Authority. A committee consists of 7-15 lay and expert members. Expert members are required to be

healthcare professionals with particular professional qualifications (hard skills). However, for both types of lay and expert members, a set of essential qualities are required in order to be appointed (soft, process and emotional skills).

13. Our research on “What constitutes expertise in research ethics and research integrity?”

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity.

One part of this work addresses the main objective in the project as “to create an e-community/database (...) of European and international experts in the different fields of research ethics and integrity”, which “should notably ensure the certification of the knowledge level of the experts.”

The main objectives are:

(1) to explore and develop indicators that are widely accepted in the heterogeneous field of research ethics and integrity representing expertise in the two areas to be implemented in the expert data base;

(2) to evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly; and

(3) address the construction, mapping, and monitoring of central expert criteria.

Our expert interviews tell us:

Database design

- Broad agreement among experts concerning the valuable aspect of establishing a database, adopting an inclusive, diverse and transparent approach to RE/RI expertise.

Required skills and qualifications:

- Most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise, holding that such expertise can take many forms (expert types, RE/RI topics, organisational levels etc.) Formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria.
- Softer and emotional skills are highly prioritized. Expert interviews show that such skills need to feature into the individual database profiles and into the final sets of criteria/indicators in some form.

Access database training & certification:

- An optional training course before database entering might be relevant, but a majority of interviewees would not make it mandatory. Several also question how to design a standardised course that would work as a common expert foundation.
- A few experts see a personal issued database certification as a good idea. Several view it as acceptable, but find it difficult to see its real value and the incentives for issuing one.
- The issue of training requirements and the issue of issuing a personal certification do not yet yield clear recommendations.
- The pros and cons of issuing a personal certification for database membership are not conclusive, based on the interview study, and the topic could profitably be a prospect for further assessment.

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Our quantitative survey tells us:

Skills and competences:

Based on the survey we may conclude that respondents value 'experience' or praxis in RE/RI assessment the most; while would like to see experts possess some theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences. When assessing required skills respondents say that experts should be personally committed open-minded and impartial people, with analytical minds to solve

the ethical/moral dilemmas that may arise as problems, while also being able to convey and deliberate their potentially diverging opinions or point of views.

- **Use of database:**

Respondents find an international database/e-community to be a very useful initiative and name various uses from the potential use to 'find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. and 'find research ethics experts for European/international networks'.

- **Database design:**

Respondents suggest that the design of the database should (pre)define all skills and expertise of the database members as well as years of practical experience is somewhat more important than specific educational background. When it comes to specific skills and competences respondents value RE/RI experience as well as previous experience in RE/RI commissions experience the most, closely followed by scientific/research experience. As for the structure of the database respondents value a number of short self-descriptions of key areas of expertise over tick-off standardized categories or a few standardized themes and open cells for filling in whatever the expert finds important.

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- **Training:**

The majority of respondents claim that training should only offered on a voluntary basis and not be made mandatory and 'any ethics/integrity training' should be accepted as opposed to a certified training by an official body.

- **Certification:**

When defining the type of certification required for the training, a majority would opt for a certification to be received at the end of the completion of the course as opposed to the requirement of certifying the teaching method.

14. Summary

Our expert interviews represented a broad agreement among experts concerning the valuable aspect of establishing a database, adopting an inclusive, diverse and transparent approach to RE/RI expertise. This has been reinforced in the quantitative survey.

As for skills and qualifications most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise. According to experts', formal and relevant education, as well as established experience within a certain RE/RI field of expertise counts as the most important RE/RI expert criteria. These have also been confirmed by the quantitative research as survey respondents value 'experience' or praxis in RE/RI assessment the most; while would like to see experts possess some theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences.

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Expert interviews have shown that soft skills need to feature into the individual database profiles and into the final sets of criteria/indicators in some form. Respondents in the quantitative survey have emphasized 'impartiality', and 'open mindedness' as well as 'personal commitment'. 'Administrative' and 'technical' skills are valued the least, while 'analytical', 'problem solving' and 'debate/deliberation' skills are highly valued therefore potentially to be included in the database design.

Experts are in agreement with respondents in our survey that an optional training course before entering the database might be relevant, but it should not be mandatory. Experts see a personal certification as a good idea and so do respondents in the survey: a majority would opt for a certification to be received at the end of the completion of an RE/RI training course.

15. List of Abbreviations

RI.....Research Integrity

RE.....Research Ethics

EAU.....Ethics Assessment Unit

Appendix 5. Summary of empirical programme and set of indicators for e-database

Report

Summary of empirical programme and set of indicators for e-database

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Work Package / Task	WP6 / Task 6.2.
Document Status	Working Document
Dissemination level	RE
	* PU - Public; PP - Restricted to other programme participants (including the Commission Services); RE - Restricted to a group specified by the consortium (including the Commission Services); CO - Confidential, only for members of the consortium (including the Commission Services).

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Document History

<i>Version</i>	<i>Date</i>	<i>Reason of change</i>
0.1	02.08.2018	Draft 01

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8. Description of Task at the GA

The European ENERI project (European Network of Research Ethics and Research Integrity) Work Package 6 addresses the main objective in the project “to create an e-community/database (...) of European and whenever relevant international experts in the different fields of research ethics and integrity”, which “should notably ensure the certification of the knowledge level of the experts.”

9. Objectives & summary of main findings

The main objectives are to explore and develop indicators that are widely accepted in the heterogeneous field of research ethics and integrity (RE/RI) which represent expertise in the two areas to be implemented in the expert database.

The main objective is to inform the database construction with empirical research as to (1) create a set of criteria for expertise in RE/RI; (2) come up with a manageable set of such criteria for database design; (3) inform the database design and strategy about potential expert/user opinions/concerns/remarks that enable and assist the better use of the database in the future. Thus, the empirical programme is aimed at creating an operable set of indicators for the database that will determine:

- How the database registration is to happen?
- What are the entry criteria (if any)?
- Who is to manage the database (if it should be managed [from a non-technical point of view])?
- What are datasets [expert criteria] to be created for better assessing the specific expertise of experts?
- What unified expertise criteria is to be applied for all experts (if any)?
- What kind of certification should the database require or offer (if any)?

WP6 team (IHS/Aarhus Univ.) has created an empirical program to address the above mentioned issues in a systematic way. The first step of the program was an extensive literature review and desktop research, followed by qualitative research interviewing experts. The next phase of the program was the quantitative survey. This was followed by a series of consensus conferences to involve potential users of the database as well as lay persons with the aim of validating our findings.

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Summary of main findings:

- The field is heterogeneous, therefore no unified or general knowledge base is to be found or created
- Evaluating expertise experience (in assessment and in practicing research) is valued over formal education;
- Formal education is relevant in philosophy/ethics and law;
- Main competences required:
 - Ethical competences (deep knowledge of national and international regulation; cases, awareness of moral dilemmas and ethical deliberation)
 - Integrity competences (deep knowledge of national and international regulation, policy and guidelines)
 - Research/science experience [having performed research activities in the past]
 - Legal competences
 - Ethics assessment/review experience [having performed ethics assessment in the past]
 - Integrity assessment/review experience [having performed integrity assessment in the past]
- Both hard and soft skills are required;
- Database should be open and diverse; self-registered; managed technically; regularly reviewed; and utilize a mix of predefined expertise categories with brief descriptions;
- Certification or training is not required as gate-keeping.

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10. Results

a. Literature review³⁶

Based on the literature reviewed Ethical Assessment Units (EAUs), the basic institutional setup for judging the ethical nature of research, are comprised of different *types* of members therefore each member needs different skills and qualifications. The expectation is that the chairperson has a set of soft skills to swiftly manage process and team, while team members have a mixture of soft and hard skills depending on their position/function within the EAU.

In general experience in ethics assessment processes is valued over qualification, and training is advised for all members. Specific knowledge/qualification is required for “ethics specialists” and “legal experts”. A key question in reference to skills and qualifications of EAU members is the validation of such skills and qualifications. While certifications may be one potential form of validation, implementing them into projects is debated. Certifications may be offered to the process/procedure, such as once training has been provided or the person has become a member of the committee. Regarding certification: procedure and training certification is favored over personal certification; while there are a number of risks and problems involved in certification, it is assumed that certification in some areas of EAUs (mainly training and process) would improve trust, transparency and credibility.

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b. Expert interviews³⁷

Based on the second part of our empirical program we have conducted a number of expert interviews³⁸. Based on these interviews, there is a broad agreement among interviewed experts to adopt an inclusive, diverse and transparent approach to RE/RI expertise. Different types of experts highlight different types of experience and competences in accordance with their field of expertise and RE/RI representation. Hence, ethics assessment/review competences are emphasized for ethics research project reviewers, while knowledge of integrity guidelines and codes of conduct are mentioned as important competences for journal editors, for instance. Despite variation, similarities in core competences and skills

³⁶ Cf. Robert Braun et al. ENERI Deliverable 6.1.: Summary of empirical programme and preliminary set of indicators for e-database, submitted 30.05.2018. Appendix 1, pp. 15-44.

³⁷ Cf. Robert Braun et al. ENERI Deliverable 6.1.: Summary of empirical programme and preliminary set of indicators for e-database, submitted 30.05.2018. Appendix 2, pp. 45-73.

³⁸ Experts are defined based on the literature as people with deliberate practice in the field (cf. Ericsson, K. A. 2006. The influence of experience and deliberate practice on the development of superior expert performance. In K. A. Ericsson, N. Charness, P. J. Feltovich, & R. R. Hoffman (Eds.), *The Cambridge handbook of expertise and expert performance* (pp. 683–703). New York: Cambridge University Press)

appear somewhat consistent across different areas of expertise. Regarding competences, the following types of acquired knowledge are suggested:

- Ethical competences (deep knowledge of national and international regulation; cases, awareness of moral dilemmas and ethical deliberation)
- Integrity competences (deep knowledge of national and international regulation, policy and guidelines)
- Research/science experience [having performed research activities in the past]
- Legal competences
- Ethics assessment/review experience [having performed ethics assessment in the past]
- Integrity assessment/review experience [having performed integrity assessment in the past]

Experts agree on the importance of a number of skills related to communication, deliberation, collaboration and management. Below, these are summarized and grouped according to hard skills (e.g. education, technical), soft skills (e.g. communicative), process skills (e.g. administrative/management) and emotional skills (commitment, open mindedness).

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Hard skills:

- Analytical skills
- Scientific skills
- Ethical commitment/thinking/abilities
- Critical thinking
- Assessment/ review

Process skills:

- Administrative/management
- Turning ideas into recommendations/practice
- Decision-making

Soft skills:

- Communicational
- Interpersonal
- Eye for details
- Ability towards deliberation
- Peace-making, conflict-resolution
- Collaboration

Emotional skills:

- Open-mindedness
- Independence
- Societal/cultural/health care awareness/impact
- Personal commitment

Formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria. An optional training course

before database entering might be relevant, but a majority of interviewees would not make it mandatory.

As for operationalization the inclusion of soft skills into the database of a peer-reviewed system was suggested in which, similarly to LinkedIn, other members of the database could add soft skills to any member of the database and support with evidence as to where and how this soft skill was demonstrated.

c. Quantitative expert survey³⁹

A questionnaire was created in January 2018 and was distributed by the European Network of Research Integrity Offices (ENRIO) network as well as was shared at the EUREC members meeting. Based on the survey we may conclude that respondents value 'experience' or praxis in RE/RI assessment the most; while they also would like to see database member experts possess some theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences. When assessing required skills, respondents say that experts should be personally committed, *open-minded* and *impartial people*, with *analytical minds* to solve the ethical/moral dilemmas that may arise as problems. Simultaneously, they should also be able to convey and deliberate their potentially diverging opinions or point of views. Respondents suggest that the design of the database should (pre)define all skills and expertise of the database members, as well as years of practical experience, as it is somewhat more important than specific educational background. When it comes to specific skills and competences, respondents most value RE/RI experience as well as previous experience in RE/RI commissions, closely followed by scientific/research experience. As for the structure of the database, respondents value a selection of short self-descriptions based on key areas of expertise, rather than tick-off standardized categories or a few standardized themes and blank cells to be filled in with whatever the expert finds important. The majority of respondents claim that training should only be offered on a voluntary basis.

d. Consensus conferences

A series of consensus conferences⁴⁰ were conducted in order to verify the expert opinion as well as offer potential user opinion to issues that were ambiguous or not operable for the

³⁹ Cf. Robert Braun et al. ENERI Deliverable 6.1.: Summary of empirical programme and preliminary set of indicators for e-database, submitted 30.05.2018. Appendix 3, pp. 74-90.

⁴⁰ Einsiedel, Edna F., and Deborah L. Eastlick. 2000. "Consensus Conferences as Deliberative Democracy: A Communications Perspective." *Science Communication* 21 (4):323-343. doi: 10.1177/1075547000021004001.

database design. The consensus conferences (CC) were conducted in four European cities in June 2018 (Aarhus, Athens, Vienna, Vilnius) to invite and involve an appropriate number of stakeholders as well as provide a good geographical spread across Europe. Altogether 50 people participated in the four CCs. Consensus was reached among participants and across venues in all six questions posed with the notable exception of Aarhus, where participants opinion diverged from the other three cities in some questions. In Aarhus criticism was also raised with the consensus conference format as limiting participants' ability to openly debate *all* issues (as opposed to the questions posed as outcome of the empirical programme) related to the potential database use and database design.

Based on the CCs potential users and other key stakeholders suggest a broad, diverse and inclusive approach to database membership. As for database structure participants suggest a semi-structured approach comprising of predefined key areas of expertise to be filled in with short descriptions, complemented with open categories to add specific skills and experience. Participants of the CCs opted for self-registration of experts (with some potential minimum experience requirements). They also suggest that the platform should offer optional training course(s) in ethics as well as other skills. Participants suggest that experience should not be quantified eg. by the number of years, cases dealt with etc, however a strong minority opinion emerged that some quality measures should also be applied to inform users about the specifics of the experience that has been quantified. It emerged that personal certification should not be applied as an entry criteria.

11. Database design and preliminary set of database indicators

a. Overview and technical translation

Database as a whole:

- There is a broad agreement to adopt an inclusive, diverse and transparent approach to RE/RI expertise.
 - *Technical translation:* the database should NOT only contain names but also clear categories of the types of expertise and experience the specific expert can offer. Database may contain a list of names with some guidance to users as to the specifics of the expertise (RE/RI/General Ethics/RRR etc. in form of a pictogram or acronym)

Database design:

- Database should
 - (pre)define skills and expertise of the database members (but some level of co-design is accepted);
 - *Technical translation:* Database should contain predefined categories:
 - Formal education in philosophy, ethics or law
 - Tercial education (institution, level of degree, title – eg. Oxford University, MA, Philosophy and Ethics)
 - Other formal education (institution, qualification, level) – eg. Training Company, Traning in ethics, Advanced level)
 - Contain short self-descriptions (focusing on evidence based experience) on key areas of expertise.
 - *Technical translation*
 - Tickbox categories [Y/N] with brief self description (max. 50 word ea.)
 - Ethical competences (description to focus on experience)
 - Integrity competences (description to focus on experience)
 - Research/science experience (description to focus on experience)

- Legal competences (description to focus on experience in EAUs)
 - Ethics assessment/review experience (description to focus on experience)
 - Integrity assessment/review experience (description to focus on experience)
- Contain specific categories for ethics experience
 - *Technical translation:* Main category+boxes, like 'work experience' on LinkedIn
 - RE experience
 - Institution (eg: University of Vilnius, EAU)
 - Task: (eg. Ethics evaluation of proposal)
 - Date
 - Reference person
 - RI experience
 - Institution (eg: University of Vilnius, EAU)
 - Task: (eg. Ethics evaluation of proposal)
 - Date
 - Reference person
 - Other ethics experience
 - Institution (eg: University of Vilnius, EAU)
 - Task: (eg. Ethics evaluation of proposal)
 - Date
 - Reference person
- Contain open categories
 - *Technical translation:* a general open category to be filled in as relevant experience to be provided on top of the above; open textual category, max. 250 words and documents for upload if needed
 - Specific & relevant experience in addition to the above mentioned
 - Documents for upload
- Contain options for peer-review & peer-rating (with transparent identification of peers)
 - *Technical translation:* Peer categories (similar to LinkedIn or star rating or other quantifiable format)
 - Peer endorsement of specific skills

- Peer recommendation
- Peer evaluation of specific experience (eg. shared EAU experience)

Database registration:

- It is advised to use an open registration process based on self-registration with some technical oversight, code of conduct and regular (annual or biannual) self-overview.
 - *Technical translation:* Database should provide for self-registration
 - For experts:
 - all categories to be filled in
 - alert to update data on a regular basis (annually or biannually)
 - For users:
 - Information to be provided if data is up-to-date
 - Information to be provided if all categories are filled in
 - For database managers:
 - Data should be verified that self description is filled in with proper information [not truth content but appropriateness]
 - Regular checks of data up-to-dateness (eg. If data is not up-dated regularly expert to drop out of database)

b. Preliminary indicators

Database indicator(s):

DI1: Inclusivity

- ✓ Experts should be inclusive of all types and experiences in RE/RI and related fields

DI2: Diversity

- ✓ Experts should be diverse (specific attention to be paid to gender and geographical distribution)

DI3: Transparency

- ✓ Data should be proper and up-to-date
- ✓ Data should be mostly predefined
- ✓ Open categories should be self-explanatory
- ✓ Documents should be up-loadable

DDI1: Definition of skills and expertise

- ✓ Skills should be tick-boxed and briefly explained

DDI2: Description of experience

- ✓ Experience should be non-quantified (eg. no number of years or number of cases options; but short quality descriptions if appropriate)
- ✓ Peer endorsement; evaluation; reflection options provided (star rating; one word rating etc.)

Expertise indicator(s):

EI1: Experience in EAU or assessment processes

✓ Types of experience:

- Assessment
- Evaluation
- Proposal writing (ethics)
- Expert opinion
- Teaching and training provision
- Specific experience in field:

- RE
- RI

○ Specific experience in ethical field

- Medical
- Digital/ICT
- Gender
- Other

EI2: Ethics/Philosophy knowledge

- ✓ Formal tertiary education in philosophy, ethics or law
- ✓ Formal non-academic training in philosophy, ethics or law
- ✓ In case of legal training: specific field eg. Data management, Human subjects etc.

EI3: Specific and relevant experience in scientific research

✓ Quantified research experience

EI4: Peer offered experience in critical thinking, ethical commitment

✓ Peer categories:

- Shared experience (eg. membership in EAU)
- Peer endorsement of soft skills (predefined categories such as):
 - Communication
 - Deliberative
 - Conflict resolution
 - Collaborative
 - Administrative
 - Emotional intelligence

Training:

- Training should be offered on a voluntary basis.

Training indicator(s):

TI1: Training option (mandatory/volunteer)

✓ *Trainings offered (pointers)*

✓ *Trainings suggested (links)*

Certification:

Certification indicator(s):

CI1: Certification of database membership

✓ No certification as entry criteria

CI2: Certification of training participation

✓ No certification of (training or database) participation

Appendix 6. Questionnaire for online survey about research ethics and -integrity expertise database

Dear ENERI e-Community member,

Thank you for your registration into our EU ENERI SYNAPSE database/E-community for experts in research ethics (RE) and research integrity (RI) and for extending your profile with an additional set of RE/RI expert descriptors.

The EU Commission wishes to build a comprehensive, inclusive and international database that is able to represent the vast and heterogeneous field of research ethics and research integrity expertise. We wish to evaluate the current database design, and we would like to seek your advice on the quality of the current expert criteria within the database.

We highly appreciate your feedback and we hope you can find time to answer five evaluative questions on the database design – the questions can be reached by following this link:
Thank you in advance!

The ENERI team

Questionnaire for online survey about research ethics and -integrity expertise database

1. To what extent do you believe the current database design capture the heterogeneous field of RE/RI expertise? To a:

Very Little Extent Little Extent Some Extent Great Extent Very Great Extent



Optional: please feel free to elaborate on the question:

2. To what extent do you believe the current database design captures the appropriate information to assess RE/RI expertise? To a:

Very Little Extent Little Extent Some Extent Great Extent Very Great Extent



3. Do you think that the information provided is useful for potential users in need of RE/RI expertise? To a:

Very Little Extent Little Extent Some Extent Great Extent Very Great Extent



Optional: please let us know what is to be added/deleted from the database information:

4. Do you believe one or more of the existing criteria/descriptors should be further specified?

Yes No



If yes, please specify which one(s): _____

5. Do you believe one or more additional expert criteria should be added to the database?

Yes No



If yes, please specify which one(s): _____

6. If you have any recommendations on how to improve the expert database, please state them below:

Thank you very much for answering the questionnaire!

On behalf of The Institute for Advanced Studies, Vienna; the Danish Centre for Studies in Research and Research Policy, Aarhus University and the ENERI consortium

