Report of Stakeholder/Focus Group Workshop in Athens, September 28/29, 2017

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Introduction

Ethical questions arise when habits of action become questionable because it is not clear what is morally required to do. Ethics in a methodically distinct way of reflection is thus a symptom of the uncertainty that accompanies changes.

There are three dimensions of research ethics that result in a meaningful classification of research ethics: First, the internal rules of science and research as a science, such as the generation of false data or the falsification of data and plagiarism. Second, the rules of research as a process that engages the world, e.g. in the sense of an experiment or a field study. Third, the question of the purpose of research as a question of the moral evaluation of possible applications. So, if research ethics is understood as the area of ethical reflection that relates to research itself, its methods, means, and goals, it becomes clear that these changes and crises affect the realm of research ethics (RI) as well as of research integrity (RI).

Against this background, ENERI endeavours to create a new culture for RE and RI by achieving an active exchange of experiences among the existing networks and between various stakeholders. The ENERI stakeholder workshop in Athens, held in September 2017, was an important step in a sequence of activities to establish a sustained platform of exchange of various actors from academies, universities, journalism, scientific journals, RECs, RIOs and funding organisations. With the stakeholder workshop in Athens ENERI brought together not only stakeholders but also representatives from other European funded projects, e.g. SATORI, PRINTEGER, DEFORM and EnTIRE. All 55 participants actively shared their perspectives, knowledge and experience in the field of RE and RI. This workshop was accompanied by preparatory and follow-up meetings of smaller focus groups to achieve the best input for the RE/RI community. The Athens workshop was structured in different SESSIONS, which combined ROUND TABLES, a PANEL DISCUSSION, GROUP WORK and TALKS. Active contribution from all participants was required during the whole workshop.

Central goal and structure of the ENERI stakeholder workshop

The central goal of the workshop was to reflect on the main questions in RE and RI from various perspectives and against different cultural backgrounds. These central questions are:

What is good and bad practice in RE/RI?
What are the challenges in avoiding bad practice in RE/RI?
Which infrastructures for RE/RI do we need?
What kind of Research Ethics Committees (RECs) and Research Integrity Offices (RIOs) do we need in Europe?
What constitutes expertise and qualification in RE/RI?
What can we learn from developments regarding training in RE/RI?
What is needed for training in RE/RI?
What tools are necessary to promote RE/RI?

Key results

SESSION I: Good and bad practice in RE/RI	Bad practice results in bad science. A **culture of good practice** in RE and RI has to be established. The main criteria should therefore be: **transparency and trust**.
SESSION II: Infrastructure for RE/RI: new challenges	More **exchange** between RECs and RIOs is needed. Stronger **EU harmonization** could help, but **cultural differences** cannot be ignored. They are given and will stay. A **collaborative approach** with input from all stakeholders is needed, in order to have guidelines that are broadly applicable, flexible and fit for all interests.
SESSION III: Training in RE/RI	The different stakeholders came to the conclusion that the following skills/competences/qualifications constitute expertise in RE/RI: 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. An open EU database of RE and RI experts could be very helpful. Certification is needed, but it should be a personally issued certification related to one's portfolio/CV.
SESSION IV: The future of RE/RI	A **core curriculum** should focus on basic knowledge in the field of RE and RI and the **advanced curriculum** could provide an in-depth analysis of the main issues on RE and RI. **Initial training for committee/board members** is the most important training, and should be a priority. For members of research ethics committees there are already established training schemes, but for members of ethics committees in the humanities and social sciences and for research integrity board members there is not much available, and this is the area where the ENERI project can make a true contribution in developing modules. From the very beginning of the discussion it was emphasised that the choice of a particular model depends on the purpose of the training: whether it should be a basic training to provide basic knowledge on the subject or should instead be a platform for mutual learning, sharing experiences, etc. This depends on the specific needs of the target audience. In line with this, it was generally thought that a training model based more on solely online participation would be more suitable for topics related to the *core curriculum,* while an *advanced curriculum* would most likely need more blended kind of training that also includes contact days and face-to-face discussions.

Outcome/results of the workshop

SESSION I: Good and bad practice in RE/RI

In **SESSION I** the participants brought together their different views about good and bad practice in RE and RI, resulting in the following conclusions:

There are many examples of **bad practices** in both fields. In RI, bad practice is mainly described in conjunction with misconduct, especially plagiarism, ghostwriting and other bad publication behaviours. In RE bad practices concern informed consent and data protection. There are also overlapping bad practices that could be observed in RE and RI, e.g. fraud and bad publication habits in general, questionable and unacceptable research practices and bad supervision and mentoring.

Good practices or desirable practices in RE and RI on the other hand were described as follows: Good is, when everybody understands that the described bad behavior is wrong. A culture of good practice in RE and RI has to be established. The main criteria should therefore be: transparency and trust.

The participants discussed in detail how to establish this new culture and mentioned in particular the following issues: All results of clinical drug trials have to be made public and have to be achieved. People have to be aware of the RE and RI issues which are related to their work. The scientific community has to realize and comprehend why RE and RI are essential and that bad practice will result in bad science. Therefore, training of experts but also of young scientists is extremely important. In particular, there is a need to establish training units for specific areas of application like research with children, research including migrants etc. There is a need to develop smart tools and support for researchers to act accordingly. Sufficient support is a necessary requirement for further developments in RE/RI. Representatives of scientific journals and journal editors demanded higher standards for publication. It is not sufficient to have more authorship guidelines because they already exist. But the practical necessity is to implement them properly. Journals should start to publish a rejection rate, and inform readers about the qualities of submitted papers. Editors should deal with plagiarism in all of its forms. Representatives from Universities claim that scientists must take care of the data they produce, as well as their respective metadata. This could help to avoid bad practice at the laboratory. A representative from Industry pointed out that only trustworthy, integrated and reconstructable data are useful. Furthermore, a collaborative approach with input from all stakeholders is needed, in order to have guidelines that are broadly applicable, flexible and fit for purpose, both for industry and academia. Representatives from science journalism stated: The central aspect that should be achieved by RE and RI is that they should generate trust. Trust not in data, since data can never be trusted, as any scientific result can be doubted, but trust in the scientific process.

SESSION II: Infrastructure for RE/RI: new challenges

A Panel Discussion referred to the question: **What kind of RECs and RIOs do we need in Europe?** The panelists and participants discussed the following key issues:

Interaction/integration between RECs and RIOs

A common goal of both RIOs and RECs is to facilitate and assure a "good practice in research". More exchange between RECs and RIOs could help to achieve this goal. A complete division of tasks between RECs and RIOs has the opposite effect. The fields of RE and RI should become closer. RIO and REC members have to figure out ways of collaborating. ENERI is a very good starting point.

Cultural differences and harmonization

RECs and RIOs in various regions come to different decisions on the same question. The reason for this could be cultural differences. Stronger EU-harmonization could help to harmonize, but this would also mean that some cultural differences have to be ignored. Cultural differences are based on history, tradition, legislation etc. They are given and will stay and should therefore not be ignored. They are comparable with differences of juridical decision according to the variety of courts and their composition. Furthermore, the value systems vary from country to country and from discipline to discipline. Nevertheless, the communities of RECs and the infrastructure where they are embedded should be prepared to find new pathways to harmonize the procedure of decision making.
The European legislation pushed RECs to more harmonized work in clinical trials reviews with the new EU Regulation on clinical trials. This model does not necessarily fit for other fields of research ethics in Europe (stricter EU legislation). Harmonization could also be reached through better organization of RECs and RIOs. Better platforms of exchange are needed, the infrastructures of Universities have to be enhanced and the role of national politics has to be clarified.

Independency of REC and RIO members

A very important principle for members of RECs and RIOs is independency. It is also very important that the members do not have any conflicts of interest.

New challenges

There is a need for more ethical reviews outside of medicine. Living in a rapidly changing world of research with ever growing sets of rules and practices, new challenges always will occur. To manage these challenges, we have to invest a lot of time and resources in training.

SESSION III: Training in RE/RI

SESSION III included group work on the question "**What constitutes expertise and qualifications in RE/RI?**" and a lecture about "**Movements and developments regarding training in RE/RI**".

The objective of the group work was to generate stakeholder input on what constitutes expert skills, competences and qualifications within the fields of RE and RI. These stakeholder inputs were then to enter into ENERI's WP6 empirical programme, which aims to explore and establish a set of relevant expert criteria/indicators for the creation of a European e-community/database of international experts.

The workshop was designed around the world café format. 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**. 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 progress.

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

- It is decisive to establish the main objective of 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 could be an idea to pilot the database in a closed environment to assist with designing the (search) tools. It was also suggested to designate the database 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".
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In terms of key **expert skills and qualifications**, the two groups discussing the matter emphasised to the following set of skills/competencies/qualifications as important:

- 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

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

SESSION IV: The future of RE/RI

The main part of SESSION IV was group work on the question "**What is needed for training in RE/RI**?" and a Round Table to the question "**What tools are necessary to promote RE/RI?**".

The following possible training models were presented in the introduction to the group work:

Model 1: *Online course* where someone/some institution is responsible for registering participants, perhaps organizing and moderating group work, and checking/giving feedback on course work. Participants could get a certificate of completion from the organizer.

Model 2: National Institutes of Health (NIH) –type *completely online course*, which has no moderators and no human resources are needed to manage participant enrollment, course work etc. one can register for the online course any time and start immediately. There are multiple-choice questions and a test to be taken and one can print out a course certificate after completion.

Model 3: *a blended course* with contact days and independent/group study online. This model requires that someone organizes and administers. Participants could receive a certificate from the organizer.

The following questions were asked:

1. What are the issues/topics you think should be prioritized in the training?
   - in core curriculum
   - in advanced curriculum
   Please consider RI/RE-overlapping topics.

2. What are the strengths and weaknesses of each training model (blended, moderated online, unmoderated online)?
   What would certification look like in each training modality?

After pondering the question for approximately half an hour, groups convened and rapporteurs presented main points from the discussions.

Following the group discussion, effective training should include:

- peer to peer (P2P) learning;
- common language;
- core principles;
- case studies.

The core curriculum should focus on the basic knowledge in the field of RE and RI and the advanced curriculum could provide an in-depth analysis of the main issues on RE and RI. Initial training for committee/board members is the most important training, and should be a priority. For members of medical research ethics committees there are already established training schemes, but for members of ethics committees in the humanities and social sciences and for research integrity board members there is not much available, and this is the area where the ENERI project can make a true contribution by developing modules.
Prioritizing the main issues and topics for the core curriculum, the group draw attention to the fact that research ethics traditionally deals with issues related to research subject protection, such as, **informed consent**, assessment of the **risk/ benefit ratio** in the field of medicine and the **main principles** on research with animals. These topics could be discussed in the core curriculum, while the advanced curriculum could cover such topics as **research on incapacitated persons** and other vulnerable groups as well as other specific topics.
The core curriculum in the field of research integrity should cover issues like **authorship**, **conflict of interest**, and the European Code of Conduct for Research Integrity. The advanced curriculum should provide in depth analysis of integrity issues, for example, more detailed analysis of the conflict of interest.
Training on legal aspects related to ethics is needed as it is vital for committee/board members to be able to distinguish the level of binding characteristics (i.e. laws, regulations, rules, guidelines and recommendations).
There are overlapping issues as well. These are: processing of data, social responsibility, interpersonal skills, and legal requirements are also very important. The mentioned basic topics could be covered by the core curriculum. And such topics as dual use, limits of researcher competence and advanced legal aspects should be in the scope of the advanced curriculum.

Group work on training modules

From the very beginning of the discussion it was emphasized that the choice of particular model depends on the purpose of the training: whether it should be basic training to provide basic knowledge on the subject or should rather be a platform for mutual learning, sharing experiences,

etc. This depends on the specific needs of the target audience. In line with this, it was generally thought that a training model based more on solely online participation would be more suitable to topics related to *core curriculum,* while an *advanced curriculum* would most likely need a more blended kind of training that also includes contact days and face-to-face discussions.

Flexibility in terms of scalability and easy repeatability were also mentioned as essential qualities of a training module. The need for the training program to be recognized and validated by an official body should be also taken into account (institutions such as EU Commission, ENRIO, EUREC were mentioned as possible bodies and recognized training programs in Germany and UK as good existing examples).

Completely online non-scheduled courses could be a preferable model to provide factual, homogenized (standardized) knowledge. The strengths of this model are that it is quick, and relatively inexpensive as it requires no human resources to manage participant enrollment and course work. Users can register for the online course at any time and start immediately and complete it in a convenient time without leaving home or the workplace.

On the other hand, this model provides no options for interactive reflection, mutual learning or discussion, which many held important for the comprehensive training of the topics in RE and RI. The completely online model is also rather rigid and needs periodic updating. The learning outcomes are evaluated by multiple-choice questions, and course certificates can be printed out after completion by the participants themselves, thus the learning outcomes are also questionable.

Online courses where someone or some institution is responsible for registering participants, perhaps organizing and moderating group work, and checking/giving feedback on course work could provide more online interaction, it could be more interesting and engaging for the participants, offering more reflection and visibility. It is possible to facilitate discussion. At the same time this model is also time saving as it requires no travelling, but in contrast to the first model discussed, it requires synchronization. It is also more labor intensive than the first one, but offers no real-life interaction as in the third model below.

The third model, *a blended course* with contact days and independent/group study online, has to be supported (organized and administered) by particular institution. This requires institutional support. It is also time consuming and not flexible in terms of dates of completion. But this model provides more reflection, face-to-face mutual learning, a more active role to the participant and greater flexibility in content corresponding actual need of participant than any other option. Therefore, this model was mentioned as preferable by some of the group members - particularly when the question is about learning to apply the ethical principles in real life cases and when it is about the RE and RI topics at a more advanced level.

It was also stated that certification may be important, but should not be regarded as a ''label''. As mentioned before, the certificate that can be printed out by the participant upon completion of the online training would be a different proof of knowledge than the certificate issued by the organizing institution upon completion of onsite training program. In both cases the validation is also important, i.e. it should be issued by the authorized and recognized institution.

SESSION V:Findings and results of the stakeholder workshop

In SESSION V the coordinators and partners of other Ethics projects funded by the European Commission gave small summaries and comments on each SESSION.

For every SESSION important findings were highlighted by the four Rapporteurs. These are the key results: During the whole workshop the relation between RE and RI was discussed. This relation is very important and must stay in focus. RE and RI both deal with the ethical conduct of research. The ENERI stakeholder workshop shows that special virtues are needed to be a good scientist. These are: competency/expertise, integrity (being honest etc.) and responsibility (which is more relevant to RE). The main question we have to clarify is: How can we address deficits in RE and RI? We are looking for a key to better practices in changing the code of science. But: This means changing a culture and this is precisely the huge challenge. To reach a better culture in RE and RI everybody has to internalize fundamental ethical principles and integrity in innovation and research activities. Responsibilities of researchers is something that has to be internalized, but must be taught. To develop/improve a culture of trust in RE and RI we have to focus on training. New and old generations of scientists have to be trained in RE and RI issues. Although the stakeholders expressed the desire that the communities of RE and RI should come closer together, current daily practice and legal frameworks need to be respected. It is clearly stated that RECs and RIOs in particular cover different fields of the same sector of good scientific practice. But with regard to education and training the overlapping issues need to be emphasized and only an integrated perspective of RE/RI and an overall view will lead to the realization of good scientific practice. This desire to improve RE/RI within the scientific community and its infrastructural framework includes the concept of ethical behaviour as a habit and not a formal check list approach. The central goal is to support the normative reflective competence of all actors such as researchers, members of RECs and RIOs, journal editors, academies, university leaders etc.

Detailed description of the workshop (based on the presentations, group work and discussion)

SESSION I: Good and bad practice in RE/RI

Round Table 1: What are the challenges to avoid bad practice in RE/RI?

Chair: Matthias Kaiser

Representative of university: Panagiotis Kavouras (NTUA)

"Measure what is measurable, and make measurable what is not so" Galileo Galilei 1564-1642.

False research findings

There is increasing concern that most current published research findings are false. The probability that a research claim is true may depend on study power and bias, the number of other studies on the same question. For more information see the article: Why most published research findings are false?

from John P. A. Ioannidis. Published: August 30, 2005 in PLoS Medicine

Scientists must take care of the data they produce, as well as their respective metadata. It helps avoid bad practice at the laboratory.

Pressure to publish

From Nature's survey of 1,576 researchers who took a brief online questionnaire on reproducibility in research: More than 70% of researchers have tried and failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments.

"Hard Sciences" proved to be the champions in reproducibility

Medicine proves not to be among the champions.

How explicitly does the Impacts section has to be described?

- Ambition is sometimes overstated in a proposal for funding
- Impact is usually extremely difficult to be quantified
- The ambition must take into account all aspects about technology, society, environment, safety, dual use, etc.

How broadly should research misconduct be defined?

- Should it be restricted to Fraud Prevention Pool (FFP), or should it include any potential breach of integrity, unethical or immoral behaviour?
- Should the level of seriousness or intentionality be considered?

EC is making efforts to engage a wide range of stakeholders from the Academia to the public

Addressing the European societal challenges tackled by Horizon 2020, building capacities and developing innovative ways of connecting science to society.

- make science more attractive (notably to young people)
- increase society's appetite for innovation
- open up further research and innovation activities

Central aims

- Raise awareness among the Greek academic community on RE&RI issues as an example of countries that need capacity building
- Institutionalization of a national code of conduct for research
- Set up of a national RI committee that will produce not act just as producer of soft and hard laws but also as a center of a research culture
- Disseminate the latest developments at the European area and beyond

Editor of scientific journal: Ana Marušić (President of the European Association of Science Editors)

- There are lots of RI problems within publishing. The motivation of authors to publish is very high, since the number of published papers decides everything regarding their scientific career.
- Editorial work is recognized as just one among less relevant advancement criteria, and there is lack of motivation on many editorial boards.
- All stakeholders, and particularly those in small scientific communities, should take responsibility for integrity and transparency of the publication process to avoid its misuse.
- Authors should take on the burden to check carefully the journal intended for submission of their manuscript, focusing on journal characteristics reflecting best open access publishing practices.
- The editors should embrace full transparency of their editorial structures and policies.
- In every institution a person should be named that is responsible for RI issues.

Representative of Industry: Anja Gilis (Janssen Pharmaceuticals)

"Integrity without knowledge is weak and useless, and knowledge without integrity is dangerous and dreadful." Samuel Johnson

Pharmaceutical industry and data integrity

We are all very well aware that reproducibility in science is an issue. And this is very important for the pharma industry. Why? It takes an average of over 20 years and 2 million dollars to bring a new product to the market. Along the road, important decisions need to be taken and projects need to be prioritized. These decisions are based on data, so it is hugely important that these data are accurate and of high quality to select the best compounds to move forward and (equally important) to stop investing in poor compounds that will not make it at a later stage anyway.

A Recent Tragedy

Poor quality data in the pharma industry can have severe consequences as we saw happening early last year in France in an FIH trail from a company named Biotrial. A healthy volunteer enrolled in a clinical trial had died as a result of severe side effects. (4 out of 5 other subjects enrolled in the same trial have serious long term neurological complications)

Call for Action

Early this year a Nature article elaborated further on this and emphasized the importance of preclinical efficacy data and evaluation mechanisms before testing new products in patients.

Translation issues affecting Pharmaceutical Industry

Now, if we look at published data that say eg that the most important factor for late phase failures is efficacy and also looking at the range of articles on poor reproducibility and the fraud cases that pop up in the media on regular occasions, the question is: how sure can we be sure of our discovery data? With the insight that "only healthy data lead to healthy patients", our senior leadership decided to take action and asked us to start up a project.

Examples of poor research practices

Janssen pharmaceuticals has a spot check program where they select pivotal decision making data from both internal and external science and do an in depth review.

Internal and external sciences

It is important to understand that the data we use for decision making is a mixture of internal and external data and we do spot checks on both.
The following examples are from both internal and external science. Internally we have not come across such examples anymore after the roll out of our quality system.
Today issues still come up in external data probably because many institutions have no mandatory training or guidelines in place (e.g for safe storage of data)

- Example 1: wrongful inclusion/exclusion of data
- Example 2 : selective reporting of replicate tests
- Example 3 : omission of data
- Example 4 : "outlier" exclusion

Prevention strategies

The drivers for poor quality are complex. The previous examples all had a component of conscious manipulation of data.
Our external collaborators may be triggered to such behavior by the need for funding for e.g. internal people may think about career advancement.
Off course this type of behavior is not the only threat to data quality. E.g. bias can also be introduced already at the time of experimental design e.g. by poor understanding of variables that impact outcomes or analyses (obvious ones are blinding and randomization) or during analysis by use of inadequate statistical methods.
Also, as mentioned before, many institutions don't have an active quality program yet and people are not aware of quality expectations.

Janssen's data quality strategy

Within Janssen we have setup a quality system to safeguard the quality of non regulated research including in depth reviews on internal and external data that are key to decision making. After this was implemented we did not see any internal examples anymore such as shown earlier on.
For external data we also try to be proactive by building expectations into contracts and by providing our internal scientists with guidelines they can share with their external collaborators. After all in Pharma industry it is all around bringing the best solutions to patients and preventing tragedies such as those mentioned in the earlier example.

Broadening our scope

In essence we started building our quality system around our internal science, then extended to our external collaborators. But since the number of external collaborations keeps growing, we realize

more and more that in order to be successful in the long term we need to evolve towards common quality expectations in the global research environment.
And for this we believe in a collaborative approach with input from all stakeholders in order to have guidelines that are broadly applicable, flexible and fit for purpose, both for industry and academia.
This will allow us to speak a common language when it comes to quality in research.

Finding the Balance

Innovation & Quality

Introducing data integrity principles in a discovery environment is often not easy.
A comment that is often heard is that research should not be steered: it should be a place with freedom to operate in order to come to innovative inventions.
That obviously is true, but on the other hand we have to realize that our company is investing lots of money in discovery and wants to make sure that in the end, trustworthy, integrated and reconstructable able data are produced.
So it is a matter of finding the right balance here: trustable data is the goal, but no 'Cinderella treatment'

Representative of Science journalism: Hinnerk Feldwisch-Drentrup (science journalist)

Trust

1. Trust in science essential today
2. Questioning creates trust
3. Processes and questions should be communicated
   - Perhaps the central aspect that shall be achieved by research ethics and research integrity is that they should generate trust
   - Trust not in data, since data can never be trusted, as any scientific result should be doubted – but trust in the scientific process, which is I think essential today
   - In order to be trustworthy, I think science should be communicated with the ambiguities that are inherent: Assumptions, uncertainties and questions should not be forgotten – in scientific articles, press releases and press reports. Perhaps there's the biggest problem with press articles, since headlines should be catchy and answers and solutions should be simple – so often there are oversimplifications that easily result in a deception of the public. In order to prevent this, I think it's essential that the oversimplification is not already done on the side of research articles and press releases.
   - I would argue that also ethical decision making and means to increase research integrity should be communicated, since messages like "human embryo manipulated" can create fear, but if ethical considerations are discussed, it will generate trust

Culture

1. Ethics committees or RI courses necessary
2. but: Culture needed
3. Transparency & communication
   - Of course institutional structures like ethics committees or ombudspersons are necessary, as are courses on good scientific practice or other soft-skills
   - But: if it's just review bodies that control scientists in their work, and one-time courses on research integrity, then research ethics and research integrity is dead
   - It has to live through a culture of ethical behavior and sound conduct, it has to live in the lecture halls, the laboratories, libraries and even the dormitories

- Enabling such a culture cannot be achieved just at research institutes and universities, but it is important that the understanding of such a culture is also grown in schools – as in all of society
- For this, transparency and communication is essential: Within labs, within science, and with society. It is necessary not only that the results of research are spread to the public, but also information on ethical dilemmas and challenges to sound science.

Challenges

1. Black and white is more attractive than grey
2. Curricula are full
3. Unsound research is everywhere (as also bad science journalism)
4. Lack of communication

Some concrete challenges:

- Curricula are full, and bad examples easily dominate good examples
- It is known that in experimental research, a large percentage of all results are invalid. The review of the statistical design of experiments often is poor, since not only in many laboratories but – at least in Germany – expertise is also missing in many ethics committees
- People often don't like to speak with each other: researchers don't like to speak with the statistician, since they would only learn that the sample size should be larger – or with the data security representative, who would block access to some data; and ethics boards or ombudspersons can be very secretive

Group work: Case studies

Questions for stakeholder groups

- Which examples of "good practices" in RE/RI did you experience in your professional practice?
- Which examples of "bad practice" in RE/RI did you experience in your professional practice?
- What is missing/what is needed in RE/RI from your point of view?

Discussion/Outcome of the group work

Bad practices

- Plagiarism, which can include textual plagiarism (taking text parts without quoting) or conceptual plagiarism (which means to taking an idea without giving credit). It also can include "Trojan" plagiarism (giving credit for a "small" idea but not for others which are also taken).
- Ghostwriting
- Being unclear about the scope of a paper, i.e. whether it is empirical or theoretical. In the example flawed empirical work was conducted but also disguised as theoretical.
- Currently the criteria for good publication are under attack, there are poor publication practices in many journals, there is a lack of common professional standards of publication
- There is a tacit and sometimes open demand by editors and reviewers to quote particular authors and publications (Favoring the "tradition" of the field)
- Papers are also rejected because of ideological reasons, because they don't fit a certain tradition or ideology (or are themselves ideological)

Good practices

- In Germany there is a law that all results of clinical drug trials have to be made public and have to be archived.

- In Germany the parliament decided to have a federal register of all clinical drug trials free of charge (the Freiburg Register)
- The University of Twente decided to have an integrated approach of RE and RI and hired an expert to set up a structure to accomplish this.
- Industry has training for young employees to raise awareness of these issues, they also have campaigns and use images (posters) to make people aware of the issue and how it relates to their work.

What is missing? What are the needs?

- Infrastructure and time cost money. Who pays for that? (The pharmaceutical industry?)
- Who is willing and has the necessary qualification to work in a REC? (e.g., lawyer) It needs time to build up the necessary competencies.
- It is not sufficient to have authorship guidelines. They exist. They also have to be implemented.
- Standards for RECs. Should they be at a European level. And it is also a question whether we need more standards or higher standards.
- A change in culture and institutions is needed, education, training, awareness
- The journals should start to publish rejection rates, and information on the qualities of submitted papers, professional standards for publishing should be created
- Higher standards in publication for editors should be established. Are there any at all at the moment?
- We have to define what authorship is. Although there are guidelines, how are they implemented? What can we do to ensure that they are implemented.
- The community has to understand why RI and RE are important. Therefore training is of utmost importance.
- It also needs tools and support for researchers to act properly. Sufficient support is necessary, e.g., bio statisticians.
- Can we have objective rules given certain traditions, ideologies and hierarchies in disciplines?
- Research is needed to understand why people behave in the way they behave, in the culture of science, science is no longer "small" but "big", an industry with rules and pressures.
- It would also be necessary to include the practice of research proposal review into RI/RE.
- Editors should deal with plagiarism in all of its forms.

SESSION II: Infrastructure for RE/RI: new challenges

Panel Discussion: What kind of RECs and RIOs do we need in Europe?

Chair: Eugenijus Gefenas

Representative of University: Inge Lerouge (KU Leuven, Member of LERU Research Integrity thematic group)

Coordination of ethics review at KU Leuven

- Research Ethics Coordination platform KU Leuven
- meetings with the chairs of the EC
- chaired by the vice rector for research
- supported by the Research Integrity & Ethics coordinator
- goal: exchange of working experiences

Infrastructure for RE and RI

- Research Misconduct Investigation Committee
- Research Integrity Committees
- Standing or ad-hoc (self regulation)
- regional, national Committees
- Regulations to protect 'good-faith whistleblowers'
- Institutional duty to provide for a climate where RM can be reported

Challenges

- Complex ethical regulations: GDPR – dual use export controls – Nagoya Protocol increased cost burdens to researchers and institutions in order to be ethics compliant.
- Research involving highly sensitive topics that may trigger public reactions. Sign-off needed from governance board?
- Harmonization of standards and procedures:
  RE: common standards of ethical review for research (SATORI)
  - accepted international ethical guidelines
  - variation in local/national laws
  - SATORI: "*Cultural factors should only be used to justify stricter requirements than those imposed by national or international laws, or by accepted international guidelines on research ethics*."

Overlapping issues

Independence: no COI

- between reviewers and researchers involved
- between reviewers and governance structures
- involvement of external members?

Competence: experienced committees with scientific, ethical and legal expertise (broad range of expertise)

⇨ providing tools/enhancing skills to handle highly sensitive situations such as RM investigations

Although these committees have their own focus, there are some important shared principles. A very important principle for all these committees, is their independence. It is very important that the members of the Committees do not have a conflict of interest.

In the context of international collaboration, it happens more and more that allegations go beyond one institution. Because you are dealing with a very confidential procedure, it is often not easy to know how to handle these situations. The important question here is whether you have a responsibility as an institution to inform the other institutions and at which point in the procedure.

Representative of a REC: Elmar Doppelfeld (EUREC)

Role of RECs in biomedical research

- The Role is rather strictly regulated by different legal or similar instruments
- Three mostly legally assigned responsibilities to RECs in relation to „good practice in research"
  - Ethical assessment of biomedical research projects involving human beings and/or using biological materials of human origin and associated data with proven scientific quality and proven conformity with law.

- RECs consider the quality of the study site – hospital, university, private surgery
- qualification of the responsible researcher and of his staff: is the researcher physician also the physician responsible for medical care of the participants, specific conflict of interest? Reaction to contigencies? Only scientific qualification or „integrity as a whole"? Only awareness of e.g. the principles of the Belmont Report or deeper education in ethics, if, to which extent? Education programs for researchers in clinical drug trials in Germany.

Harmonization by legislation

- EU Commission failed for 35 years to introduce harmonized regulations for the field of RECs.
- One common complaint is different decisions by RECs on the same application. It is not unusual that different bodies assessing the same application come to different conclusions: science, jurisdiction
- Difference between ethics and law – known since antiquity, but until today not solved. Cultural differences are based on history, tradition, legislation, last but not least on religion, they are given and will stay. The EU-Legislation can harmonize the procedure but can never cancel the moral positions of citizens in the Member States. However, EU Legislation may shrink the possibilities of RECs to intervene.
- Would somebody like to turn back to medieval harmonization when only the church decided on „good" and „bad" with stringent legislation?

Scope of ethics review

There are new challenges for RECs. These challenges could be answered and are already met by RECs e.g. in some German universities, where the REC of that university is competent for all research involving human beings and personal data. Infrastructure is provided, the REC is familiar with ethical and legal problems of that research, the scientific quality of a submitted project including the researcher has to be assessed by independent specialists.

Representative of a RIO: Asaël Rouby (ENRIO)

Investigation of RI-Level of regulation

Challenges: Do we have the same value systems?

- Independent from country
- Independent from discipline

Science Europe. The Working Group has three main focuses:

- Promoting research integrity;
- Preventing misconduct, and
- Increasing transparency when investigating cases of misconduct.

Challenges for the future

Briefing Paper Science Europe: "The challenge now is for European governments, funding agencies and research institutions to follow through on their commitment to research integrity with tangible actions. No one actor can feasibly address all of these actions. Rather, a collaborative effort by all concerned will be required."

The European Code of Conduct for Research Integrity

ALLEA: "The present revision is motivated by current developments in the European research funding and regulatory landscape, changing institutional responsibilities, and evolving review procedures"

Amsterdam Agenda: "promote discussion and to coordinate efforts to improve research integrity on a global scale."

Representative of science management: Nik Claesen (European Association of Research Managers and Administrators (EARMA)

Key challenge

- Rapidly changing world of research with ever-growing sets of rules and practices
- All of these rules and best practices must be followed up, managed and reported on
- Do we train highly specialist researcher to do a bit of everything? (legal, finance, project management, communication, …)
- And leave the project management to project managers, the financials to financial experts, etc.

Research Ethics and Integrity within EARMA

- Topics within the conference are a very hot topic for our community
- Setting up a thematic group to spread best practices and exchange information about the rapidly changing needs in ethics and integrity at the operational level (February 2018@Brussels)
- In collaboration with all interested stakeholders including the EC to provide input and feedback in both directions
- Focus on the operational side within research-performing organisations
- Goal is to implement the changes in rules and practices in the best way possible with the least amount of overhead (financial and research time)

SESSION III: Training in RE/RI

Group work: What constitutes expertise in RE/RI?

Chairing of the groups: Robert Braun, Tine Ravn

Objective of the group work

The objective of the workshop was to generate stakeholder input on what constitutes expert skills, competences and qualifications within the fields of research ethics and research integrity. These stakeholder inputs 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.

The workshop was designed around the world café format. 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 attached 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.

Outcome/results

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 progress.

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

- It is decisive to establish the main objective of 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 could be an idea to pilot the database in a closed environment to assist with designing the (search) tools. It was also suggested to designate the database 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 inclusive/exclusive 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 mirror 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/competencies/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

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 personally issued certification related to one's portfolio/CV

Questions for the four groups

Skills and competences

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

Qualifications

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

Certification

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

EU database of RI/RE experts

1. In order to build a 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 possess to become a member of the database? (education, experience, teaching, process and emotional skills?)
2. What are "must have" criteria and qualifications?
3. Which criteria and qualifications would it be "good to have"?
4. Would European institutions – including yours – benefit from more standardised practises, processes and qualifications?
5. Should there be any particular research ethics and integrity training programs or upgrading of skills required? (Initial training? Recurring upgrading?)

Current findings of ENERI, WP 6

Tine Ravn

Work package 6 (WP6) addresses the main objective in the call "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"

Objectives

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

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

Preliminary approach to expert qualifications and certification:

Certification equals a "qualified network membership" for which the incentive forces to registrar foregrounds a user based focus on knowledge exchange and professional community building

Broad and inclusive approach to expert qualifications

Skills/qualifications/competencies:

- What constitutes an expert? (specific types of education, years of practical experience, teaching experience, interpersonal skills etc.)
- Who is to define expertise? How to take into account changing contexts (cultural, epistemic, geographical) and ongoing developments etc.?
- Use of self-descriptions vs. pre-defined categories? (or both)
- Self-assessment vs. nomination?
- Standardisation of qualifications vs. non-standardisation? (a broader discussion of standardised practices and processes)
- General impression:
    - open, inclusive and diverse approach to expert criteria – not "just consolidating the ivory tower of ethical expertise"
    - many types of experts (practitioners, policy/law experts, academic experts etc.);
    - a long number of different topics (RE/RI - publication ethics, data management, FFP, QRPs, developing teaching curriculum, moral philosophy, law, bibliometric etc.)
    - different types of skills (hard, soft, process, emotional etc.)
    - expertise at different organizational levels (local, national, international)

Training/certification

- Preliminary expert member training (mandatory or optional training to set a common ground?) vs. no training? – difficult to design a "formula curriculum", experts should already be representatives of their field, a diploma does not equal expertise
- Certification (training or personal?) vs. no certification – discussed whether this will be an incentive for participating → relates to the difficulties of standardisation

Database

Objective?: a) E-community/platform/national and international contact point for sharing best practices/knowledge b) and a database/registry for searching for experts from the part of the EU commission and beyond (broad user base)

- Monitoring of experts?
- Mirror the complexity of RE/RI "in and around research"
- Different implications of exclusive/inclusive criteria

Skills/qualifications

- 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

Certification

- Positive approach towards certification → but personal certification related to portfolio/CV

Developments in Training for RE/RI - From Fraud to Social Responsibility

Deborah Oughton (Research Director, Centre for Environmental Radioactivity, NMBU, Norway)

Developments in RE and RI over the past decade

- The number of courses in ethics offered to students at universities has increased across all levels of education
  … but few are given as an obligatory part of training

… content varies widely

- An increasing number of National and International Codes of Content and Ethical Guidelines exist, including for specific disciplines.

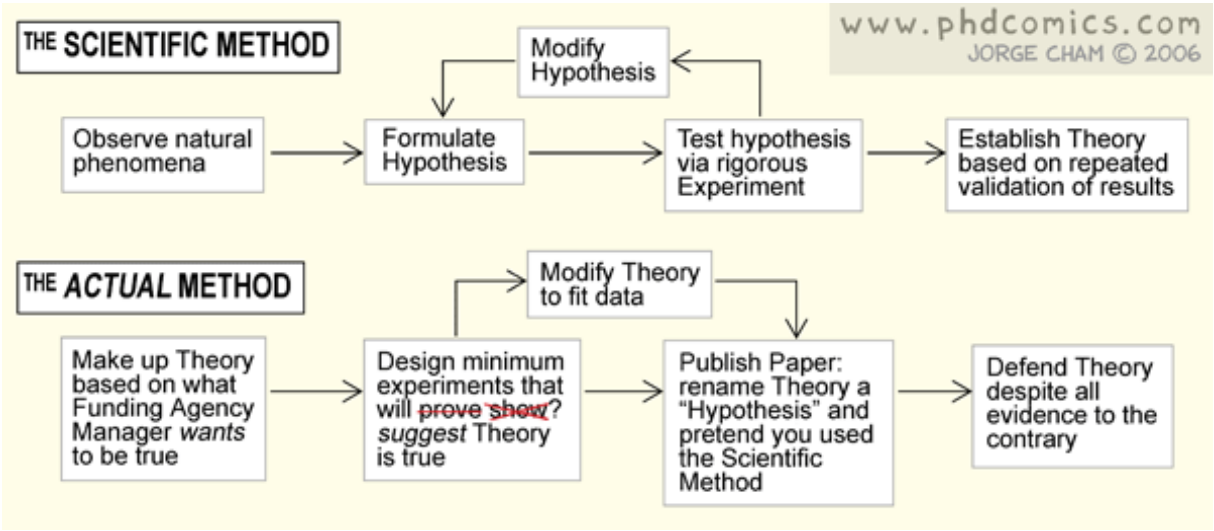
… but differences in implementation between research institutions

Research Ethics for PhD students in Norway – 25 years at the Mat. Nat. Faculty, UiO

- In the early 1990s a course in Philosophy of Science (Vitenskapsteori) was obligatory for all students taking a PhD in mathematics or natural sciences at UiO
- 1998 – the course became no longer obligatory
- 2007 - reintroduced as an obligatory part of the PhD training at UiO (5 ECTS)
- 2009 - a course in Research Ethics became an obligatory for PhD students at all Norwegian Universities

What do we teach now and how has that changed over the past 10 years?

What is Science?



Frauds in Science

- What is research fraud?
- Why does it happen?
- How often does it happen?
- How is it controlled?

Mertonian Norms (CUDOS)

- Communalism: scientific knowledge should be shared as widely and quickly as possible
- Universalism: independent of the personal or cultural status of the scientist
- Disinterestedness: scientific results should be free from personal or corporate biases
- Originality: Research should be novel
- Scepticism: Results should be vigorously tested

Could new standards threaten norms of science?

- Commercial pressure
- Publication pressure
- Limited encouragement to engage in teaching and public outreach

PLACE: The new norms (Ziman)

- Proprietary – not communal
- Local – reseachers concentrate on local technical problems, which may not contribute to general understanding
- Authority – vested in a managerial hierarchy, not the individual researcher
- Commissioned – to solve specific problems
- Expert – rather than a creative person

Ethical Issues in Publication

- The most common source of arguments and misconduct allegations
- Responsibility of co-authors is a key issue in fraud cases

Conclusions

- Appreciated by the students – less so their supervisors
- Make time for small group discussions
- Important for teaching and creating a culture of openness
- Case, cases, cases…
- Mixture of classic cases and topical cases
- Need for training pre and post PhD (e.g. supervisors)

SESSION IV: The future of RE/RI

Group work: What is needed for training in RE/RI?

Three possible training models:

Model 1: *Online course* where someone/some institution is responsible for registering participants, perhaps organizing and moderating group work, and checking/giving feedback on course work. Participants could get a certificate of completion from the organizer.

Model 2: National Institutes of Health (NIH) –type *completely online course*, which has no moderators and no human resources are needed to manage participant enrollment, course work etc. One can register for the online course atany time and start immediately. There are multiple-choice questions and a test to be taken and one can print out a course certificate after completion.

Model 3: *a blended course* with contact days and independent/group study online. This model requires that someone organizes and administers. Participants could receive a certificate from the organizer.

This SESSION was chaired by Erika Löfström and Simo Kyllönen (University of Helsinki), Eugenijus Gefenas and Vilma Lukaseviciene (University of Vilnius), and Nicole Föger (ENRIO). First, Erika introduced the tasks and objectives of WP 4 on training and capacity building, the target groups and intended learning outcomes of the envisioned core and advanced curricula for research ethics and integrity board/committee members, and three potential training modalities (namely, moderated and administered online course, non-moderated/administered

online course, and blended course). Second, the participants were split into four break-out groups, which considered one of the following questions:

1. What are the issues/topics you think should be prioritized in the in a) the core and b) the advanced curriculum? Please consider RI/RE-overlapping topics

2. What are the strengths and weaknesses of each training modality (blended, moderated online, unmoderated online)? What would certification look like in each training modality?

After pondering the question for approximately half an hour groups convened and rapporteurs presented main points from the discussions. These are summarized below:

Group work on training topics

Following the group discussion, effective training should include:

- peer to peer (P2P) learning;
- common language;
- core principles;
- case studies.

The core curriculum should focus on basic knowledge in the field of RE and RI and the advanced curriculum should provide an in depth analysis of the main issues on RE and RI. Initial training for committee/board members is the most important training, and should be the priority. For members of research ethics committees there are already established training schemes, but for members of ethics committees in the humanities and social sciences and for research integrity board members there is not much available, and this is the area where the ENERI project can make a true contribution to developing modules.

Prioritizing main issues / topics for the core curriculum, the group draw attention to the fact that research ethics traditionally deals with issues related to research subject protection, such as informed consent, assessment of the risk/ benefit ratio in the field of medicine, as well as the main principles on research with animals. These topics could be discussed in the core curriculum, while the advanced curriculum could cover such topics as research on incapacitated persons and other vulnerable groups as well as other specific topics.

The core curriculum in the field of research integrity should cover issues like authorship, conflict of interest, and the European Code of Conduct for Research Integrity. The advanced curriculum should provide in depth analysis of integrity issues, for example, more detailed analysis of the conflict of interest.

Training on legal aspects related to ethics is needed as it is vital for committee/board members to be able to distinguish the level of binding characteristics (i.e. laws, regulations, rules, guidelines and recommendations).

There are overlapping issues as well. These are: processing of data, social responsibility, interpersonal skills, and legal requirements, which are also very important. The basic topics mentioned could be covered by the core curriculum. And topics such as dual use, limits of researcher competence and advanced legal aspects should be in the scope of the advanced curriculum.

Group work on training modules

From the very beginning of the discussion it was emphasised that the choice of particular model depends on the purpose of the training: whether it should be a basic training to provide basic knowledge on the subject, or should rather be a platform for mutual learning, sharing experiences,

etc. This depends on the specific needs of the target audience. In line with this, it was generally thought that a training model based more on solely online participation would be more suitable to topics related to *core curriculum,* while an *advanced curriculum* would most likely need a more blended kind of training that also included contact days and face-to-face discussions.
Flexibility in terms of scalability and easy repeatability were also mentioned as essential qualities of a training module. The need for the training program to be recognized and validated by the official body should be also taken into account (institutions such as the EU Commission, ENRIO, and EUREC were mentioned as possible bodies and recognized training programs in Germany and the UK that are good existing examples).
A completely online course could be the preferable model to provide factual, homogenized (standardized) knowledge. The strengths of this model are that it is quick and relatively inexpensive as it requires no human resources to manage participant enrollment and course work. Users can register for the online course at any time, start immediately and complete it in a convenient time not leaving home or workplace.
On the other hand, this model provides no options for interactive reflection, mutual learning or discussion, which many held to be important for the comprehensive training of the topics in RE and RI. The completely online model is also rather rigid and needs periodical updating. The learning outcomes are evaluated by multiple-choice questions and the course certificate can be printed out after completion by the participants themselves, thus the learning outcomes are also questionable.
Online courses where someone or some institution is responsible for registering participants, perhaps organizing and moderating group work, and checking/giving feedback on course work could provide more online interaction, which could be more interesting and engaging for the participants, offering more reflection and visibility. It is possible to facilitate discussion. At the same time this model is also time saving as it requires no traveling, but in contrast to the first model discussed, it requires synchronization. It is also more labor intensive than the first one, but offers no real-life interaction as in the third model below.
The third model, *a blended course* with contact days and independent/group study online, has to be supported (organized and administered) by a particular institution. This requires institutional support. It is also time consuming and not flexible in terms of dates of completion. But this model provides more reflection, face-to-face mutual learning, a more active role of the participant and flexibility in content corresponding to the actual needs of participant than any other. Therefore this model was mentioned as preferable by some of the group members - particularly when the question is about learning to apply the ethical principles to real life cases and when it is about RE and RI topics at a more advanced level.
It was also stated that certification may be important, but should not be regarded as a ''label''. As mentioned before, the certificate that can be printed out by the participant upon completion of the online training would be a different proof of knowledge than the certificate issued by the organizing institution upon completion of onsite training program. In both cases the validation is also important, i.e. it should be issued by the authorized and recognized institution.

Round Table 2: What tools are necessary to promote RE/RI?

Chair: Erich Griessler

Representative of University: Inge Lerouge (KU Leuven, Member of LERU Research Integrity thematic group

Tools to promote RE/RI

- Determining and defining RE and RI
  - *Comparative analysis of CoC within LERU universities (2015 - Itziar De Lecuona, Erika Löfstrom, Katrien Maes)*
    Much variation in the content of the CoC
    Access to the CoC on the university websites not always easy: ⇨ public access is crucial - < 3 clicks away from homepage
    Research community is not always aware of the existence of the CoC/ guidelines ⇨ Raising awareness of code by informing researchers through education, training, website
    Q: signed confirmation needed that it has been read?
- Guiding towards RE and RI
  - provide structured training opportunities
  - encourage mentoring
  - foster discussion
  - information channels
  - tools to support researchers
  - training to promote responsible conduct of research (RCR):
    - Format and content vary across institutions
    - Face to face or online or a combination (blended format)
    - experience-based workshops/ cases
    - Integration of ethics/integrity components in leadership training (Zürich) and supervision training (UCL, KULv)
    - Evolution towards more mandatory training
    - Recommendation LERU-study CoC: Use the expertise within integrity/ethics-related commissions for training and developing educational material
  - mentorship: It is important that RI and RE is also taught in the context of everyday practice of science !
    - Review the data !
    - ¾ of the mentors '*do not review the data of their students*' (*Wright et al.: 2008) (a study of closed cases from the ORI files from 1990 to 2004)
    - Regularly discuss RI and RE with your PhD researchers (e.g. Research Integrity Checklist as part of the PhD charter that all incoming doctoral students sign at the start of their doctoral studies at KU Leuven).
  - Foster discussion
    - Some universities (eg UvA) are running a research integrity climate survey, e.g. The Survey on Organizational Research Climate (SOURCE). One could do this for local discussion purposes, to collect data at a group, department or wider level, to look for trends over time, to help identify areas for further discussion or action. The actual data collected may be less important than the awareness-raising and local discussion.
  - Information channels: website, newsletters
  - Tools to support researchers:
    - Institution data storage policies are vital
    - CLUE recommendation: > 10 years
    - Keep raw data and unprocessed scans
    - Digital vault for working with sensitive data
  - Tools to support researchers in data management
    - Electronic lab notebook
    - Online template for DMP

    - Research Data Services: e.g. University of Edinburgh
- Monitoring
    - *Bad people will not be affected by regulations – only by sanctions.*
      Enhanced monitoring by: checking gel photos – set rules and review before submitting for publication
    - Enhanced monitoring by:
        - systematic screening of master/PhD thesis for plagiarism with Turnitin by some faculties
        - appointing an ethics advisor/advisory board during project life time (sometimes independent ethics advisors difficult to find → database?)

Representative of Industry: Anja Gilis (Janssen Pharmaceuticals)

„Integrity is doing the right thing, even if nobody is watching."

Janssens' DDI quality system

A good quality system is in fact a continuous improvement cycle (because it needs to be flexible over time to fit the needs of the changing environment) and it consists of different building blocks:

- It all starts with the right culture. Most scientists are very proud of their work, but it takes more to be successful. They need to be aware of the risks of eg. poor data storage practices for patent protection and the importance of data transparency for good decision making.
- This awareness will trigger them to think for themselves and to help look for solutions.
- As an example, we have organized poster campaigns, where we have posters with visuals or slogans on data integrity. There is also a contest for scientists and the one with the best contribution wins a price.
- We have organized FTF training sessions for all our scientists worldwide: interactive, eye opening, quiz questions: these received good feedback, people have fun and reach out after the sessions. We also ask management to be present at these sessions and give an opening speech on what data integrity means to them. To have visible management support is critical for success.
- Participation is key!
- Once scientists understand the importance of research integrity they are usually open for a next step which is a gap analysis of current practices. This will help them and their management identify the risks within their own work.
- During such gap assessment we see for example that scientists are struggling with safe data storage. They are keen on keeping all data and soon run into storage space issues which on its turn leads to suboptimal storage of data.
- As a next step, multidisciplinary teams were established to tackle the gaps and to leverage best practices seen in other groups.
- Once the workstreams have a proposal for a solution, this first gets reviewed and approved by senior leadership since they are the ones accountable and without their support it will simply not work.
- Then the next question is: how do we measure our success of our quality program? How have we progressed against the baseline and where should the next priorities be?

Key success factors

- Role Models: Senior leaders sponsorship & support
  "Talking the talk, walking the walk"
- Mandatory education for all staff
- Community participative communication
- Partnerships: Quality, IT, Biostatisticians, Communications, …

- Simple, sustainable solutions and *"fit for purpose"* guidance
  By scientists, for scientists
- Transparency: central data sharing
- Spot check program (= measure of success)
- Speak up culture (hotline)

Towards a common quality system for non regulated research?

EQIPD - IMI Project

European Quality in Preclinical Data

- First IMI consortium completely dedicated to improving preclinical Data Quality
- Joint undertaking by big pharma, CROs, academia and scientific associations
- Proof of concept in Neuroscience and Safety, facilitated by a Quality Management System
- Expand R&D-wide if successful
- Participants:
  - 11 EFPIA partners
  - 8 applicants (10 universities, 7 CROs, 1 scientific society
  - 7 associate collaborators
  - 5 advisors

Representative of Science journalism: Hinnerk Feldwisch-Drentrup (science journalist)

- Encouragement & incentives: Academic credit should encourage for example corrections – and speaking about failures. Researchers often hesitate to speak about upcoming projects, but there should be interest in constructively discussing these with colleagues & critics.
- Strategies that increase transparency: like public databases + information infrastructures. Registration and publication of results of studies can possibly increase integrity & ethical conduct not only of clinical trials, but all types of studies.
- Stories: These are essential to understand the basic challenges of ethics and integrity. In order to understand that there is not normally "ethical" and "unethical" research, but all types of shades of gray, telling stories can be of great help not only for academics, but also for the general population. I would encourage scientists and members of ethics boards as well as ombudspersons to speak more openly about challenges they encountered when preparing or reviewing research projects, in order to allow the general public to have insights into the debates that come along with many research projects.

DISCUSSION:

What should be integrated in the curricula?

Training is very important

Create a culture of research integrity

Training for all researchers in one course

Where can they go to, if they see something is not in order regarding RI?

Senior researchers follow supervision training

How to create acceptance

Top down approach

SESSION V:Findings and results of the stakeholder workshop

Summary of the Workshop results

Chair: Guy Widdershoven (coordinator EnTIRE)

Rapporteur SESSION I: Philip Brey (SATORI and SIENNA coordinator)

The discussion about the relation between RE and RI is very important:
In SATORI RE and RI are treated as separate issues. RE and RI both deal with the ethical conduct of research. The ENERI stakeholder workshop shows: In RE and RI special virtues are needed to be a good scientist. These are:

- Competency/expertise
- Integrity (being honest etc.)
- Responsibility (more RE)

The big question is: How can we address deficits in RE and RI?
We are looking for the key to better practices in changing the code of science. Changing the culture is not easy. Everybody has to work together to get a better culture in RE and RI.

Rapporteur SESSION II: Maria Ribeiro

What kind of RECs and RIOs do we need in Europe?

Major Focused Topics

- Need to foster a culture of ethics and integrity in research
- Responsible and justifiable research
- Importance of respecting the fundamental ethical principles and integrity in innovation and research activities
- Different level of regulation in the European countries
- Training and support highly specialist researcher´s responsibilities
- RECs more focused on participant protection; RIOs more focused on behavior of the individual researcher and/or research process
- Prevent misconduct as the best way to keep TRUST in Research(ers)

Major Conclusions

- Improve (develop) research integrity policies at national and international levels
- Promote a culture of integrity in research practice by improving ethical awareness and reflection through the education of new generations of scientists
- Need to harmonize standards and procedures on ethics research review and codes of conduct
- RECs and RIOs have different tasks with common/overlapping issues
    - Keep the structure of research ethics and integrity as it is (for better effectiveness)
    - Need to "close" the gap between RECs and RIOs
- Create a (working) platform with the common tasks/challenges

SESSION III: Hub Zwart

Are we in a integrity crisis? Husserl already talked about this crisis. The system as such is facing a kind of crisis in integrity.

Resilience

- Challenge or crisis?
- Scientific research: challenged or impossible profession?
- Culture of deliberation
- Traumas → working-through
- Educational tools

Ethos or enforcement?

- Internalisation (learning by doing)
- Weber: Perverse systemic incentives can only be counteracted if the number of responsible professionals driven by internalised values and motives is large enough

Compliance with standards?

- Standard operating procedures
- In research compliance is both encouraged (research should be in accordance with normal science standards and protocols, guideline-compatible, etc.) and discouraged (focus on originality, ambition, opening up new terrains, crossing borders, non-conformism, etc.)

Educational tools

- Mutual learning exercises (transdisciplinary, transgenerational)
- Trustworthiness, reliability, responsibility, veracity, transparency are part and parcel of scientific research methodologies
- Engaging, interactive tools, learning by doing, integrity laboratories
- Sustainable open access platforms for learning materials

Rapporteur SESSION IV: Caroline Gans Combe

- Training needs
- You must know who you are targeting and what your message is
- Markets and targets
- Using audit to build SOPs
- A balance score card for RE and RI

DISCUSSION:

- How can we achieve an ethos?
- Education as an integrity laboratory.
- Ethos and change of culture: except for medicine (medical ethics is standard) in many other fields it is not. Changing slowly. There is a whole generation of scientists that did not have that background/education - the younger students e.g. There is ethical education for medical doctors and lawyers. Why not for scientists?

report prepared by the ENERI office and the ENERI beneficiaries

Workshop Agenda

Thursday, Sept 28

9.00-9.15	Registration and welcome coffee
9.15-9.30	Welcome address by the host Costas Charitidis
9.30-09.45	Welcome address by the European Commission Isidoros Karatzas
9.45-10.15	Introduction to the workshop by the coordinator of ENERI Dirk Lanzerath
SESSION I:	**Good and bad practice in RE/RI**
10.15-11.15	Round Table 1: What are the challenges to avoid bad practice in RE/RI? Chair: Matthias Kaiser Universities: Panagiotis Kavouras Editor of Scientific Journal: Ana Marušić Industry: Anja Gilis Science Journalist: Hinnerk Feldwisch-Drentrup
11.15-11.30	Coffee Break
11.30-12.50	Group Work Case studies in breakout groups to tease out the ethics and integrity problems Chairing of the groups: Nicole Föger, Erika Löfström, Erich Griessler
12.50-13.00	Presentation of the group work
13.00-14.15	Lunch Break
SESSION II:	**Infrastructure for RE/RI: new challenges**
14.15-15.45	Panel Discussion: What kind of RECs and RIOs do we need in Europe? Chair: Eugenijus Gefenas Science Management: Nik Claesen Universities: Inge Lerouge REC: Elmar Doppelfeld

RIO: Asaël Rouby

15.45-16.15h Coffee Break

SESSION III: Training in RE/RI

16.15-17.30 Group Work:
What constitutes expertise and qualification in RE/RI?

Chairing of the groups: Robert Braun, Tine Ravn

17.30-17.45 Presentation of the group work

17.45-18.00 Wrap-up and closing remarks

Dirk Lanzerath, Costas Charitidis

20.00 Joint Dinner, Location: Chocolat Royal

Friday, Sept 29

8.30-8.45 Welcome Coffee

8.45-9.00 Current findings of ENERI

Tine Ravn

9.00-9.30 Movements and developments regarding training in RE/RI

Deborah Oughton

9.30-9.45 Discussion

SESSION IV: The future of RE/RI

9.45-11.00 Group Work: Guided brainstorming to the question:
What is needed for training in RE/RI?

Chairing of the groups: Isidoros Karatzas, Nicole Föger, Erika Löfström, Eugenijus Gefenas

11.00-11.10 Presentation of the group results

11.10-11.30 Coffee Break

11.30-11.45 The audit process and strategy for Directorate General for Research & Innovation

Marina Zanchi

11.45-12.30 Round Table 2: What tools are necessary to promote RE/RI?

Chair: Erich Griessler

Universities: Inge Lerouge

Industry: Anja Gilis

Science Journalist: Hinnerk Feldwisch-Drentrup

12.30-13.30	Lunch Break

SESSION V: Findings and results of the stakeholder workshop

13.30-14.30	Summary of the workshop results Chair: Guy Widdershoven Rapporteur SESSION I: Philip Brey Rapporteur SESSION II: Maria Ribeiro Rapporteur SESSION III: Hub Zwart Rapporteur SESSION IV: Caroline Gans Combe
14.30-14.45	Closing of the workshop Dirk Lanzerath, Costas Charitidis

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16.30-18.00	**Public Event** Location of the Public Event: NTUA (Zografou Campus), Central Amphitheater of the Administration Does global ethics lead to reliable and responsible research? Miltos Ladikas **Panel Discussion** Chair: Costas Charitidis – Ana Marušić (European Association of Science Editors) – Elmar Doppelfeld (Chair of EUREC) – Søren Holm (University of Manchester)