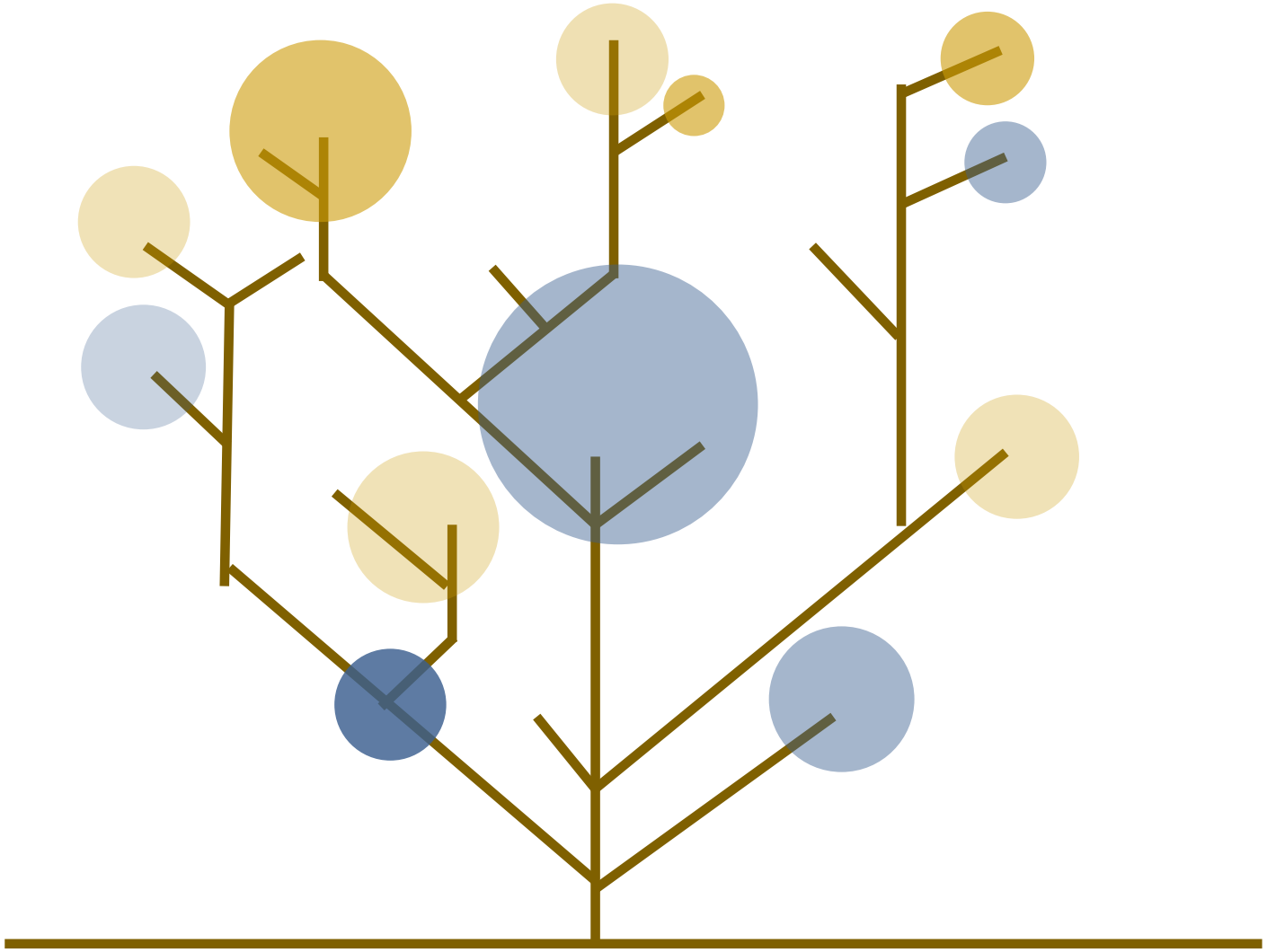
START WITH THE DECISION TREE



HOW TO USE THE DECISION TREE

ENERI DECISION TREE

eneri

This project has received funding from the European Union's H2020 research and innovation programme under grant agreement No 710184.

OUR MISSION

- A **good researcher** should reflect the ethical issues and challenges before, during and after conducting the research.
- **Research Ethics Committees (REC)** should help researchers in doing good research.
- **Research Integrity Offices (RIO)** should assist researchers to monitor their research.

With the ENERI decision tree, we want to help researchers, REC and RIO members to think about ethical questions and challenges that might arise during a planned research project. The tool has been developed to complement the RE&RI manual and intents to help users to find the appropriate ethical questions more quickly.
Users will find guidelines, codes and other helpful references for many different research areas, guiding them through a proper ethical reflection. Based on the relevant information the user can decide which parts of the planned research project require ethical reflection and taking into account existing national specificities, it is then up to the user to find the appropriate best solutions to deal with the identified ethical implications based on the national context, EU and international regulations and standards.

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HOW TO USE THE DECISION TREE

This document is a PDF document. The easiest way to use it, is by clicking through the relevant boxes that stand for the different steps/aspects of research. Beside this, it is also possible to read the whole document by just scrolling down.
The decision tree is a living document. That means we will update it from time to time with additional information. You can read it online on our website (www.eneri.eu) and you can also download it there.

FIRST: DECIDE WHICH BOXES ARE RELEVANT FOR YOUR SITUATION

Some researchers already have ethical knowledge and an awareness of the appropriate ethical questions. Some are totally new in this field. Furthermore, ethical questions arise on different levels: before, during and after conducting the research. With our decision tree we offer the opportunity to find tailor-made solutions for your situation: You can decide which boxes to click and where to start.

SECOND: FIND OUT WHAT IS BEHIND THE BOXES

You will find not only the most important ethical questions and aspects to consider, but also the relevant codes, guidelines, policy papers and other literature. Please study the material we offer carefully.

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PLANNING THE RESEARCH

THE ACTUAL RESEARCH PROCESS

CLICK here, if you are designing your research project…

The content of this box should be relevant for everyone – out of context!

QUALITY ASSURANCE & DISSEMINATION

APPLICATIONS & MONITORING

If your research project already started, CLICK here…

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The button at the upper left brings you back to the beginning.

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RESEARCH IN BIOTECHNOLOGY FOR URAL AND FOOD OUTSIDE OF THE ICAL SECTOR)

RESEARCH ON HUMAN REMAINS

An example: If you click on “planning the research” this page opens up and gives you the possibility to decide again what is relevant for you and study the relevant information…

You can easily click through the subjects relevant for your research and go deeper…..

STUDY DESIGN AND OBJECTIVES, AVOIDING BIAS

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Click back…

ETHICAL PRINCIPLES AND CENTRAL ISSUES

ASPECTS TO CONSIDER

For each research field we offer you information on ethical principles and central issues + we give you lists with the relevant literature, laws, policy papers, codes and guidelines to read.

LAWS, CODES, POLICY PAPERS & GUIDELINES

The button at the bottom brings you back to the respective subpage.

Click next…

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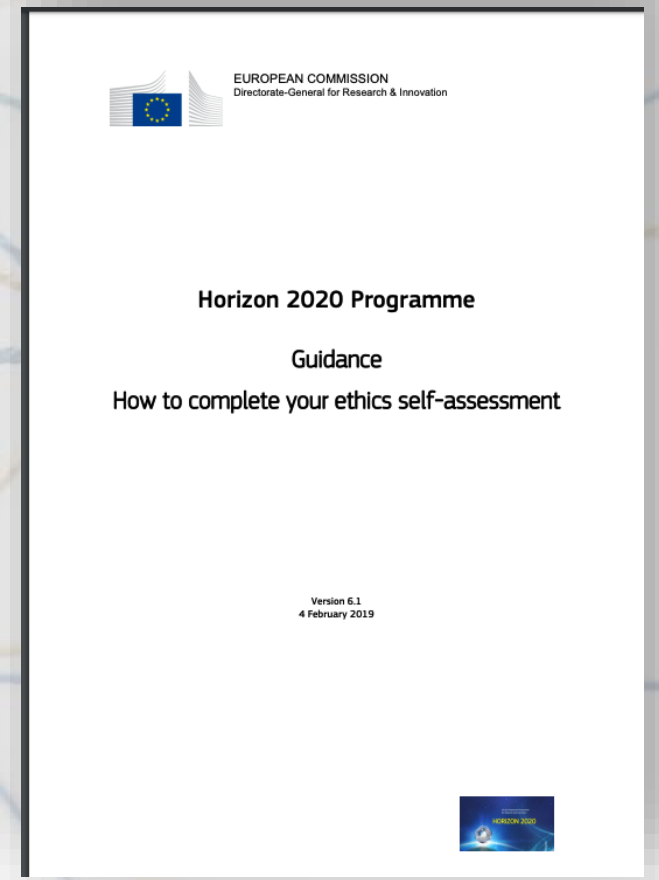
BEFORE YOU START…

We hope our decision tree will help you as a tool to find the right ethical questions and answers quickly. Of course, there are other ways to find out about the ethical implications of your research project.

We strongly recommend all researchers to work not only with our decision tree, but to also study the H2020 Ethics self-assessment and the European Commission's guidelines on Ethics and data protection carefully.



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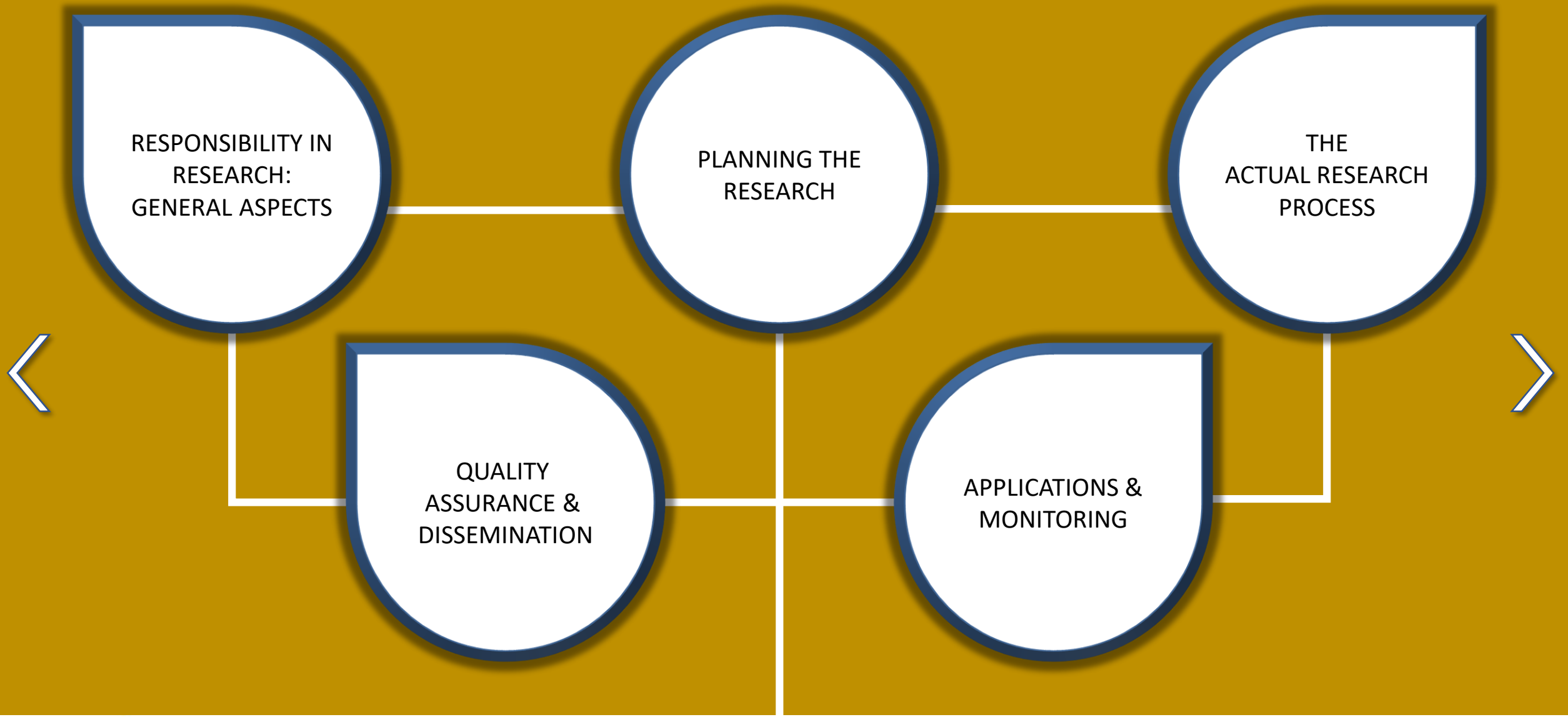
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CENTRAL ISSUES

Research is not only a specific methodology but also a social practice. We as researchers know that we all hold differing opinions based on a multiplicity of beliefs; we are products of our cultures and societies, our education and our thoughts; we are rational and emotional. Our work, however hard we try to avoid it, is situated in that existential reality. Science has tried hard to present itself as impartial in its aims and methodologies, but as researchers with integrity, we have to raise important ethical questions with regard to research as a process and a social practice. They are as important as questions about the methodologies for our particular disciplines, the knowledge of the literature of our subjects, and meticulous attention to detail in lab work, analysis, and the presentation of our research discussions and conclusions. They form the starting points for the imperatives towards responsible research and innovation (RRI) and professionalism in science.

The answers, in a pluralist society, will be personal but they are, of course, situated in research cultures and practices; methodological paradigms and research manners produce institutional norms that researchers absorb and to which they conform (or with which they struggle). As professional researchers, we must participate in this construction of the context of science. We must also find ways to include the broader societies in which our work is located. At the very least, we are funded by society; at a higher ideal, we are contributing to that society and autonomy demands that individuals have a voice that is heard in establishing the trajectory of their lives and lived environment.

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ASPECTS TO CONSIDER

General aspects to consider:

- How far is it possible to rise above bias?
- Who sets the agenda for my work?
- Whose voices are heard in setting that agenda?
- Whose interests are served by the research?
- Do any of the answers to these questions cause me, or others, concerns?
- Is it necessary for me (my institution, my funder, my colleagues, my friends and society) to be worried about what I am doing, or the reactions of others to what I do?
- How would I talk about, and defend what I do to others?

There is also a set of formal standards that are in place, with external regulators (often jurisdictionally specific):

- Do I know the ethics and law standards that apply in the different countries (or regions) where I am undertaking the work?
- What are the formal requirements?
- What permissions are needed, to whom do I apply, and when?
- Are there any informal requirements or expectations in the jurisdiction in which I will work?
- If I am going to challenge these, am I doing it deliberately and with good (defensible) reasons? (And am I prepared to face the cost of challenging the requirements?)

We need to ask ourselves, whom do we consult about our proposed work? This is a multi-layered question:

- How am I going to discuss the formal methodologies of my work, and with whom?
- If I am working in an area that might generate intellectual property that I (or my funder or institution) might wish to exploit commercially, will I need to maintain a circle of confidentiality around the work?
- How far can, and should, I share my ideas with colleagues as I develop them?

There are conceptual questions that we contribute to through the act of researching, and so must consider:

- What is the evidence that I will be creating?
- What am I claiming about that information?
- How am I justifying the claims that I am making?
- Why do I think that the claims that I am making are solid?
- What are the weaknesses in what I am doing and what I am saying?

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THE LEGAL FRAMEWORK OF RESEARCH

There is no single international convention or agreement on research, enforceable with formal sanctions, for all research in all jurisdictions. There is a patchwork of requirements that differs radically between different jurisdictions, and, more troublingly, between disciplines. However, there are some elements that one should think about at the outset.

INTERNATIONAL (AND REGIONAL) HUMAN RIGHTS

INTERNATIONAL ETHICS STANDARDS OPERATING WITH LEGAL EFFECT

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INTERNATIONAL (AND REGIONAL) HUMAN RIGHTS

The Human Rights narrative - i.e. framing of international relationships between States and (to a more limited extent) between people - has been developing since, essentially, 1945. It is, at its highest iteration - in the Universal Declaration of Human Rights (UDHR) - an Inter-State set of undertakings about acceptable behavior towards individuals, and increasingly the environment. It is, at this level, often a matter of political power and political relationships; there is no Universal Court of Human Rights, for example; an individual citizen has limited rights to enforce her rights under the UDHR. The UDHR is developing into sectoral covenants and undertakings that develop the concepts. The enforcement is again a matter of politics.

At the regional and state level, there are enforceable human rights. For example, the European Convention on Human Rights (ECHR) is an implementation and development of the UDHR in the context of the Council of Europe. These rights are enforceable through the European Court of Human Rights (ECtHR). The decisions carry sanctions, albeit often only enforceable as a matter of politics. Individual states parties implement the requirements of the ECHR (and the decisions of the ECtHR) through their domestic law - often as binding constitutional law, enforceable through the courts of the jurisdiction.

LINKS

- Charter of Fundamental Rights of the European Union
- European Convention on Human Rights (ECHR)
- International Covenant on Civil and Political Rights (1966)
- Universal Declaration of Human Rights (UDHR)

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INTERNATIONAL ETHICS STANDARDS OPERATING WITH LEGAL EFFECT

During the Nuremberg Trials, the judgement relating to those who committed atrocities under the guise of 'research' during World War Two contained a ten-point code that research including human participants should follow (in 1947). This was accepted by the World Medical Association in the Declaration of Helsinki (1964). This has been revised in 7 versions (plus two Notes of Clarification), most recently in the 7th revision of 2013. Whereas this is not legally binding of itself - it is a declaration of an association of particular professionals - it can become legally binding through the operation of contract law, particularly employment contract law. An individual may be required to observe the requirements of the Helsinki Declaration as part of the conditions of her employment, with the sanctions of that law applying in the event of a breach of the requirements.

Likewise, professional bodies often have codes of guidance on research ethics and integrity. Again, these are not generally binding instruments of international law (for example, the Code of the British Association of Psychologists or of the American Psychological Association). However, to be a member of such a body - and this is often a mark of one's standing in a particular field - it is likely that the member must, again, as a matter of contract law, agree to be bound by the Code of Conduct, and thereby the rules become legally enforceable.

LINKS

- American Psychological Association: https://www.apa.org/ethics/code/ethics-code-2017.pdf
- British Association of Psychologists Code of Ethics and Conduct: https://www.bps.org.uk/news-and-policy/bps-code-ethics-and-conduct
- Nuremberg Code: https://history.nih.gov/research/downloads/nuremberg.pdf
- World Medical Association Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

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REGIONAL REQUIREMENTS

Different nation states create binding rules for different aspects of the conduct of research. Likewise, as part of the creation of the European Research Area (ERA), the European Union has created a number of research-related Regulations and Directives and has developed guidelines and practices governing research. Very often these concern, inter alia, the operation of Research Ethics Committees, different aspects of research practice (for example, requirements relating to consent, or to the processing of personal data, or the use of animals in scientific experiments).

LINKS
EU:

- Directive 2010/63/EU on Protection of Animals used for Scientific Purposes https://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/directive/en.pdf
- GDPR EU General Data Protection Regulation https://gdpr.eu/

National:

- Netherlands – WMO Medical Research Human Subjects Act: https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/laws/medical-research-involving-human-subjects-act-wmo
- Norway – Health Research Act https://www.etikkom.no/en/library/practical-information/legal-statutes-and-guidelines/the-health-research-act/

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ETHICAL PRINCIPLES AND CENTRAL ISSUES

When research is conducted with a cross-national or international methodology or when in a multicentral study the research centres are based in different countries, various ethical concerns may arise. The dissemination of findings might be evaluated differently in the countries concerned (i.e. due to political, religious or ethical sensitivities). It is not given that research undertaken in one jurisdiction is allowed (under the same conditions, or perhaps at all) in another place. For example, there are restrictions on the use of human embryonic stem cells in research in Germany or Italy that are not the case in the UK. In most cases, cross-national or multicentral will be undertaken within networks of researchers, and local knowledge is available. However, it may be that legal advice is necessary on a jurisdiction-by-jurisdiction basis. The bigger problem is creating a methodology that can operate across the jurisdictions, subject to the different requirements of the local law and Research Ethics Committees (RECs), without jeopardising the integrity of the work. In the absence of international RECs or courts, it is often left to researchers themselves (with their advisers) to negotiate appropriate research practice between jurisdictions.

One problem area relates to data linkage across scientific fields - for example, where researchers using data in the field of medical sciences wish to link with social science data where issues of individual consent may be less stringent in some countries. Furthermore, potential risks for research subjects might be considered differently from country to country or from culture to culture. Also, the relation between public and private funders may be considered differently in the countries concerned. Furthermore, aspects of data protection are handled in different ways when there are variations in the data protection regulations and the data protection practice. When organisms, seeds or other biomaterials are exchanged in a certain study, this might encounter various regulations with regard to environmental or biodiversity related regulations. There might also be programmes of access and benefit sharing that have to be considered carefully. Finally, materials with historic value or archaeological human remains may rise national emotions and/or ethical concerns in the community addressed.

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ASPECTS TO CONSIDER

The following aspects need to be considered:

- Do I/we have good legal information and advice about our research in the different jurisdictions where it will be undertaken?
- Do I/we have access to local knowledge to negotiate the requirements for the research across the project and project consortium?
- Are these requirements adequately addressed in the Consortium Agreement?
- Will the research related activities undertaken in or in cooperation with non EU countries and does this cross-national research raise ethical issues?
- Will any local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.) be used for the study?
- Does the study include the import or export of any material – including personal data – from non-EU countries into the EU?
- In case this research involves low and/or lower-middle income countries, are any benefit-sharing actions planned?
- Is it risky for individuals to take part in the study, considering the situation in the country?
- Does the research meet the data protection regulations and the informed consent procedures that might differ from the EU standards?

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GENERAL ETHICAL PRINCIPLES WITH REGARD TO AUTHORSHIP

One of the most ubiquitous challenges in research integrity is accurate authorship attribution. Authorship of publications is, alongside obtaining grants, the key element of career progression in research due to the way the current system is designed. This means that authorship is very important. It is so important to some researchers that they are happy to be named as authors when they did not contribute anything substantial - or anything at all - to a particular paper. These are 'guest' authors or honorary authors (an ironic name as there is nothing honorable about it). It is also so important that junior researchers are sometimes left off author lists when they did contribute substantially, because they aren't deemed to have 'earned' authorship yet or their inclusion could dilute the credit given to the other authors. These are 'ghost' authors. Finally, ghostwriters are often paid by researchers to write articles in the expectation that they will not be credited.

It should be noted that authorship paradigms differ between disciplines and what counts as a substantial contribution in one discipline may not count as one in another. For example, most papers in medical journals have several authors. In contrast, philosophy papers often have only one author (Cutas & Shaw 2014) and sometimes pages of acknowledgments. Often the people mentioned in these footnotes have actually contributed more than many of the authors of clinical research papers. The following sections focus more on the disciplines of science and medicine, because it is here that the problem is probably worst. Authorship issues exist in all fields, however.

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GUEST AUTHORSHIP

Authorship is ambiguous and its accurate attribution is heavily dependent on hierarchy. Junior researchers who are new to writing papers for journals are to a large extent at the mercy of senior researchers, who pass on dominant authorship practices to their new disciples. If a lab leader or department head expects to be named as an author on every paper written by any of his staff, he will probably get what he wants. If a junior researcher is brave enough to question why the senior should be credited when he hasn't even read the paper, a mid-level researcher might attempt to justify the authorship by arguing that none of them would have a job if the professor wasn't providing the grant and the lab facilities. This might seem reasonable to a junior researcher, but it is not (see Guidelines section below). Authors have to contribute to the writing of a paper. The hint is in the word itself.

The phenomenon of guest authorship raises great difficulties for researchers. Not only can they come under pressure to acquiesce in adding people who are not authors to papers, it is often junior authors who actually submit papers to journals. Most journals now ask for a statement that all authors contributed substantially. If the submitting researcher ticks the box next to this statement (or inserts such a statement in the paper) he or she is violating research integrity (and many would say is also guilty of misconduct). But for many researchers, the alternative could be losing their job and career. Guest authorship in itself might seem like a relatively unimportant transgression, but it implicates all other authors in deception (and possibly fraud) and allows senior researchers to unjustly pad their CVs, sometimes widening the gulf in power between them and junior researchers. For any given paper, adding ghost authors will dilute the perceived contribution of the actual authors. And of course, if junior researchers come to believe that guest authorship is ok, this might be the first step on a slippery slope to other research misbehaviors.

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GHOST AUTHORSHIP

The flip side of guest authorship is ghost authorship, where researchers who deserve to be named as authors are not given this recognition. It is even possible that a junior researcher could end up doing most of the research on a given project, writing most of the paper and submitting it, but still not end up as an author (an indignity rendered even worse if the paper also features guest authors). While guest authorship is freeriding, and dilutes the visible contribution of the other authors, ghost authorship amounts to theft of intellectual property. If someone has contributed, he or she deserves credit. Furthermore, the person who did most of the research is normally the guarantor of that research.

In the case of paid ghost authors, the problem is rather different. Often, such authors are happy not being named on papers as they are paid for their services. But equally, if they do all or most of the work on a paper, it can often mean that the other authors are all rendered as guest authors (One study found that no named authors would admit they were the authors of one particular paper on cancer.) The main issue with guest authors is not lack of recognition, but that the named authors may not have conducted the research, much less read the paper in question. This is a magnified version of the last issue mentioned in relation to junior researcher ghost authorship.

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CONTRIBUTORSHIP AND THE FUTURE OF AUTHORSHIP

In addition to establishing who should and shouldn't be an author, there is the secondary problem of what order the authors should be listed in. Generally, the first author is assumed to have done most work, while in many disciplines the place of last author is regarded as indicating seniority. Again generally, most researchers would prefer not to be the middle author. But different disciplines and journals have different conventions. Some use alphabetical order, some use descending contribution order, and some use the first/senior author paradigm. Even when researchers agree amongst themselves that they should all be named as authors, the specific order can result in disagreement. It is now possible for people to be named as "co first authors" or even "co senior authors" so that a paper could actually have four (or more) authors in the two 'best' positions. Generally, discussion about who should be included as an author, and potentially the order of authors, should be discussed in advance (though subject to modification) in order to avoid disappointment and conflict later.

Because of the ambiguity surrounding the concept of "substantial contribution", some journals are moving towards contributorship statements that are published alongside traditional author lists. These statements make it clear(er) who did what on a given research project; e.g., DS did that, DT did that, BP did this. As well as providing clarity for readers, requiring authors to provide these details also encourages reflection about who deserves actual authorship, and acts as a disincentive to include guest authors and exclude ghost authors. An honest contributorship statement on a paper with guest and ghost authors would have to include a sentence like this: " X and Y did nothing. Z did everything else but isn't on the author list because we paid him." Contributorship statements also allow for recognition of effort that does not qualify researchers for authorship, such as providing biosamples or machinery.

However, while journals are moving towards contributorship, they are not yet moving away from authorship. Contributorship lists are often buried at the end of articles behind a paywall, while authorship lists are highly visible. It has been suggested that *replacing* authorship lists with contributorship statements would be the best solution, as it would replace a flawed and ambiguous system of attributing credit with a less vague and more specific one. But paradigms are resistant to change, and "author of 20 papers" will sound better than "contributor to 20 papers". For the foreseeable future all researchers should treat authorship seriously and sensitively.

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GUIDELINES

Because of all of these issues, various organisations including the International Committee of Medical Journal Editors (ICMJE), Committee on Publication Ethics (COPE) and World Association of Medical Editors (WAME) have developed guidelines that set out what criteria must be met for someone to qualify as an author (at least for those publishing in biomedical journals).

The ICMJE recommends that authorship should be based on the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

[http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html]

The creation of these guidelines is good in the sense that they provide a benchmark that can be used to guide whether someone should be named as an author. But they are not unproblematic. First, what constitutes a substantial contribution? Substantivity is subjective. I might get upset if I think I have made a substantial contribution and you think I haven't (Indeed, if I'm right and I'm not credited I will become a ghost author). While rigorous application of the ICMJE guidelines should prevent 'total' guest authorship where the named person made zero contribution, it will not weed out authors who merely read papers and gave a few comments.

It has also been pointed out that these authorship criteria might be *too* rigorous. Imagine that someone has a great idea for a study, someone else conducts the research, and someone else again writes and submits the results. None of these people would qualify as an author. The contributorship statement (see below) for this paper would say something like "X had the idea, Y did the research and Z wrote this paper. But none of us are authors" (Shaw 2011).

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LITERATURE

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When human participants are involved in research projects it is necessary that they are informed, that their participation is considered as voluntary, and that the treatment includes the potential of only minimal risk and burden. This applies to invasive medical research as well as to observational studies or interviews in the social sciences and the humanities. Human participants in research studies are considered as autonomous beings that need to be respected as persons and not as mere research subjects by the researchers and by the research design.

In order to ensure the awareness and voluntariness of the participants' participation, the concept of informed consent was developed in the context of RE. Informed consent now has become the most prominent concept of both medical ethics and medical law. Apart from a few exceptions, interventions - whether for therapeutic or research purposes - are considered ethically unjustifiable without prior informed consent. Legally, they are usually rated as personal injury. How specific the information needs to be provided depends on the study design and the objectives. The potential subject must be informed about the right to refuse participation in the study or to withdraw his or her consent to participate at any time without reprisal. The concept of informed consent requires a basic understanding about the research concerned. This means that the consent is considered not only as a formal but also as a well-informed agreement. Therefore, a requirement of ethically justified research with human participants is that researchers provide the participants with well-prepared information on the research activity, whatever research methodology is being used. Equally, children, adolescents, and cognitively disabled persons must be provided with information that is appropriate to their age and competencies, bearing in mind the environmental context, differing experiences, and evolving capacities of each person. In the case that a research participant is not capable to give informed consent, the researcher must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject and the research cannot instead be performed with persons capable of providing informed consent. All research participants should be given the option of being informed about the general outcome and results of the study.

The procedures to obtain informed consent differs in various cultures. These cultural differences need to be taken into account (i.e. the involvement of other family members). In all research projects, it should be borne in mind that there is an unbalance power gap between the researcher and the participant.

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The following aspects need to be considered:

- How will the informed consent be articulated (language, clearness, completeness, age appropriate)?
- What is the state of the research participants (able to give consent, not able to give consent, minors, vulnerable groups etc.)?
- Are the participants patients or healthy volunteers?
- What are the possible benefits for the participants?
- What are the possible risks and burdens for the participants?
- How is a clarification about voluntariness of participation and opportunity of withdrawing at any time communicated?
- Will a compensation be paid and is this an incentive to participate in the study?
- What is the type of information asked or investigated about and how sensitive is this information (personal, life style, health etc.)?
- How is personal data protected (data protection: anonymisation, pseudoanonymisation etc. / data used in interviews, videos, tapes etc.) and who is responsible for them?
- How will the process of recruitment of volunteers be organised?
- What are the criteria of inclusion and exclusion of human participants?
- How is the balance of power between the researcher and the human participant addressed?

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Animal suffering should be avoided in research. The main general ethical guidelines for research considering the use of animals are the so-called three R's, which have to be carefully considered in the design of the study:

- Replace the use of animals with alternative methods (such as research with tissues or computer simulations), or avoid the use of animals altogether.
- Reduce the number of animals used to a minimum, to obtain information from fewer animals or more information from the same number of animals.
- Refine the way experiments are carried out, to make sure animals suffer as little as possible. This includes better housing and improvements to procedures which minimise pain and suffering and/or improve animal welfare.

There are many laws and regulations that have to be consulted when applying for a permission to use animals for research, and these vary between countries and institutions. There are also different regulations for different lab-animals, and usually strict requirements for institutionally approved specialists to ensure housing and living conditions.

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The following aspects need to be considered:

- Are the three Rs carefully considered?
- Are there alternatives like cell lines, tissue samples or simulations?
- Are the numbers of animals kept to a minimum?
- What animals are used – is it the most suitable species, and what are the relevant institutional, national and international laws and regulations?
  - Primates
  - Vertebrates
  - Wild animals
  - Endangered species
- Are genetically modified organisms, Crispr-Cas modified organisms or cloned animals used, and are the institutional, national and international laws and regulations followed up?
- If laboratory animals are used, are the housing and living conditions of animals conducted by formally approved specialists?
- Are there possible implication for biological diversity, wild animals and/or endangered species?

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LAWS, POLICY PAPERS, CODES & GUIDELINES

Laws and regulations differ between countries and between institutions – these must be consulted. Besides that, the following guidelines could be useful to consult:

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In particular in genetic engineering and synthetic biology severe ethical issues may arise that have to be considered before and during the research process. Biotechnology uses findings of biosciences and advanced technologies to generate products and processes for the benefit of society. The potential of these technologies touches the entire spectrum of life including agriculture, food processing, medicine, and many other areas. Although genetically modified organisms have many benefits, they are also considered as potentially harmful to the environment, to other organisms and to human health. Modification and transfer of genes by using advanced methods has created continuing disagreement on a global scale. The new field of synthetic biology also includes aspects of the engineering sciences and may combine biological and technical impacts on organisms, environment and the society. Ethical concerns such as informed consent, confidentiality, access and benefit sharing, intellectual property rights, privacy and liability are required to consider. Products of biotechnology may also be subject to secondary or dual use. Researchers need to consider the potential military use but also the misuse for bioterrorism (i.e. the use of newly created pathogenic organism).

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Therefore, the following aspects need to be considered:

- May the newly created organism harm other organisms, the environment, or human beings?
- May they be subject to secondary or dual use?
- Does synthetic biology include particular negative impacts on the society?
- What kind of societal impact will a potential industrial implementation of the results have?
- Are there any culturally or socially controversial or sensitive impacts (privacy, property rights, rights of indigenous groups)?
- Are aspects of access and benefit sharing carefully considered?
- Does the research have an international impact and may conflict with international regulations?
- Are all data protection aspects considered?
- Are all necessary approvals stored in the records?
- Does this research involve the use of methods that may cause harm to humans including research staff?

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ETHICAL PRINCIPLES AND CENTRAL ISSUES

Engineering research may affect society and the environment significantly, in intended and unintended ways. Possible repercussions borne out research outcomes and technologies need to be considered, including so-called hard impacts (physical impacts on environment, health and safety) and soft impacts (impacts on social realities and ideals such as justice, equality, individual rights, identity, etc.) (SATORI 2015). General ethical principles relate to minimising harm to humans, animals and the environment, and seeking solutions compatible with the principles of sustainable development. As engineering researchers often work in close collaboration with industry, conflict of interests may also be particularly relevant. The World Federation of Engineering Organization's code of ethics contains four basic principles: demonstrate integrity; practice competently; exercise leadership; and protect the natural and built environment.

Some of the sub-fields in engineering, like chemical engineering, nanotechnology, nuclear technology and robotics and AI, compromise particularly high degrees of uncertainty about long-term effects and/or side-effects on the environment, public health, public safety, and future generations. Taking a precautionary approach, it is important considering a wide range of possible ethical implications (e.g. by applying an ethical matrix). In addition, Responsible Research and Innovation (RRI) approaches should be considered.

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GENERAL ASPECTS TO CONSIDER

Therefore, the following aspects need to be considered:

- May the newly created technology harm organisms, the environment, or human beings?
- To what extent are the technologies attuned to the needs, aspirations and views of society? How are risks and benefits for society balanced?
- What kind of impacts do the developed technologies have on society, also on a global scale?
- May the developed technologies be subject to secondary or dual use?
- What kind of societal impact will a potential industrial implementation of the results have?
- Are there any culturally or socially controversial or sensitive impacts (privacy, property rights, justice)?
- Are aspects of access and benefit sharing carefully considered?
- Does the research have an international impact and may conflict with international regulations?
- Are all data protection and privacy aspects considered?
- Are all necessary approvals stored in the records?
- Does this research involve the use of methods that may cause harm to humans including research staff? Are alternative safer mechanisms considered?
- Are possible unforeseen long-term-effects or side-effects on the environment, public health, public safety, and/or future generations considered?
- Are there any economic interests in particular when there are co-operations with industry planed?

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LAW & LEGAL ASPECTS TO CONSIDER

Here the question is about ensuring that the research and development outlay can be recouped - at least, how far that outlay can be attempted to be recouped - and the major legal issues are around patents. At the outset, given the potential value involved, it is advisable to take advice from experts at the earliest point in an invention cycle; likewise, it is imperative that any activity is kept confidential (including publishing papers, or presenting ideas at a conference or workshop, for example) before the patent application is filed with the relevant patent offices.

Patents are a monopoly, a market-lead-time, whereby the holder of the patent can, for a limited period, exploit the invention without competition from others. This means that the individual can either exploit the product or process directly, or can licence others to produce or use the patented material. The social deal, to balance the enormous power granted to a patent owner, is that the way of creating the patented product or process must be disclosed in the application, and the patent is only granted in relation to the claims made about the product of process. Therefore, competitors can invent around a patent (making the patent obsolete), or prepare to compete with the patent owner as soon as the patent ends.

Whereas copyrights are created simply by the creation of a tangible form of an expression of an idea, and are not registered, patents are registered rights and are created by patent offices in each jurisdiction where the invention is to be exploited. (There is no “world patent”, and patents are only enforceable in the jurisdiction where they are granted.)

To gain a patent, the invention must:

- Be **Novel** - it cannot exist in the “state of the art”;
- Involve an **“inventive step”** - it cannot be obvious to someone skilled in the area; and,
- Be **capable of industrial application**

There are some restrictions applying differently in different jurisdictions:

- It must be an invention, not a literary work;
- It cannot be a mathematical formula;
- It must be an invention and not a discovery (although this is not applied in all jurisdictions);
- It’s exploitation cannot offend morality or order public (not applicable in all jurisdictions);

There are also particular restrictions on the patenting of certain life science processes and biotechnologies.

The other side of patents in research is that one must also be aware of patents that are valid in relation to materials or processes that one’s own research use. For example, if working on genetic material, it is possible that the gene is ‘owned’ under a patent and a licence could be required.

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In genetic engineering and synthetic biology for agricultural and food purposes, several ethical issues may arise that have to be considered. Ethical issues then also extend to potential production, uses, and trade. With the ambition to identify potential issues “upstream” and make adaptations if necessary, considering these issues upfront is a benefit, and is therefore recommended. Biotechnology uses findings of biosciences and advanced technologies to generate products and processes for the benefit of society. The potential of these technologies touches the entire spectrum of life including agriculture, food processing, medicine, and many other areas. Biotechnology is often used as a general term for modification of the genome of an organism, e.g. by transgenic modifications through recombinant DNA techniques, or nowadays through e.g. genome editing (CRISPR-Cas9). In agriculture, more traditional breeding techniques have been used for a long time and are not widely disputed. However, the modern biotechnology with targeted changes of the genome has been met with wide skepticism. One of the major concerns is the safety of the process, and the outcome. In 1975 the Asilomar conference initiated work on the regulatory framework for this kind of research. A framework for lab safety has evolved and can be found here. All research with genetic modifications of animals and plants has to comply with the safety standards which hold for all countries in the EU. Containment of the organism which is researched is one of the main issues. This is particularly salient when dealing with small organisms like insects, or microorganisms like bacteria.
When a genetic modification has been achieved in the laboratory, different international and national regulations apply to field trials, import, and marketing of the products. The Cartagena Protocol on Biosafety covers the transfer, handling, and use of GMO. Although genetically modified organisms have many benefits, they are also considered as potentially harmful to the environment, to other organisms and to human health. A risk assessment covering among others the possibility of gene flow is called for by the appropriate regulations, like the EFGSA and EU Directives and regulations (see below). Pro-active research would require an early assessment of these issues. Modification and transfer of genes by using advanced methods has created continuing disagreement on a global scale. The new field of synthetic biology also includes aspects of the engineering sciences and may combine biological and technical impacts on organisms, environment and the society.

Ethical concerns such as safety (including food safety), risk to biodiversity and environment, access and benefit sharing, intellectual property rights, privacy and liability are required to consider. Products of biotechnology may also be subject to secondary or dual use. Researchers need to consider the potential military use but also the misuse for bioterrorism (i.e. the use of newly created pathogenic organisms). Since the societal benefits and side-effects may be viewed differently by different stakeholders, a participatory stakeholder engagement is recommended. The principles depicted in an ethical matrix tool are normally covering these diverse aspects, which need to be considered.

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Therefore, the following aspects need to be considered:

- Does this research involve the use of methods that may cause harm to humans, including research staff?
- May the newly created organism create harm to other organisms, environment, or human beings?
- May the modified organisms have a detrimental effect on biodiversity?
- May they be subject to secondary or dual use?
- Does synthetic biology include particular negative impacts on the society?
- What kind of societal impact will a potential industrial implementation of the results have?
- Are there any culturally or socially controversial or sensitive impacts (privacy, property rights, rights of indigenous groups)?
- Are aspects of access and benefit sharing carefully considered?
- Does the research have an international impact and may conflict with international regulations?
- Are all data protection aspects considered?
- Are all necessary approvals stored in the records?

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Relevant laws and regulations vary to a certain extent between countries. However, most of them within the EEZ will comply with the EU regulations mentioned below. One country, Norway, has a Biotechnology Act which requires, in addition to the usual risk assessment, also considerations of sustainability, societal benefit, and ethics.

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In anthropological and archeological fields especially, research on human remains is useful for understanding human history and development. Human remains include intact skeletons, parts of skeletons, remains after cremations, and other human biological material that is retained by museums and collections, or which emerges as a result of archaeological and other investigations. While the dead cannot be mistreated directly, research on human remains requires respect for the person of whom the remains were a part, and the material must be treated with discretion and dignity. Further, ethical aspects regarding respect for the individuals, groups and cultures that the remains represent should be considered. Human remains may be viewed differently in different countries and cultures, at local, regional or national levels. Groups who historically have been oppressed or humiliated may have reasons for being particularly sensitive to research which could represent a risk of this history being continued or repeated. Insight into and awareness of these views and sensitivities are therefore essential. Another ethical issue that needs to be considered is that human remains are non-renewable sources of knowledge, and that excavations may obstruct possibilities for future researchers.

Law and Legal Issues

Human remains are subject, in many cases, to arrangements regulated under criminal law and specific agencies dealing with the regulation of the clinical and research use of human tissue. This covers the use of human tissue removed from living patients or donors, the use of human remains donated in life for scientific research after death (i.e. before burial or cremation), and scientific research on human remains exhumed from burial sites. Further, there are regulations concerning the creation of tissue banks.

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Therefore, the following aspects need to be considered:

- Do the methods of excavation, the storage facilities (including records and archives) preserve the remains to the highest possible degree?
- In cases where material is rare and unique, are alternatives to possible destructive fieldwork considered? Is there available material in other collections that can serve the same research purposes as the remains being considered for excavation?
- Are the descendants properly consulted?
- Are the wishes of the local community or of relatives or guardians of the dead considered?
- Do the value of the intended knowledge gain outweigh possible destruction of rare material or other possible undesirable consequences?
- Are there any data protection and privacy aspects touched?

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The design, methodology and goal of a study include important aspects that may cause ethical concerns. Scientific character already has normative implications, since it is not acceptable to involve human subjects into a study even with minimal risk and burden when the concept of a study is not scientifically sound. These considerations should also include the issue that a bad study design leads to a waste of economic resources. Furthermore, the social value of the approach and the goal are a matter of ethical consideration next to the aspect of gathering knowledge as such as a more general value of humanity.

Against this background, the role of the researcher and of a study's sponsor has to be reflected. The researcher must confirm his or her necessary qualifications, which not only have to be based on the skills in the scientific discipline, but must also carefully reflect whether the research process meets all requirements of good scientific practice and whether there is any conflict of interests.

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Therefore, the following aspects need to be considered:

- How does the design and the type of the study look like from an ethical perspective?
- What are the goals of the study?
  - What are the economic interests?
  - What are the social interests?
  - What are the therapeutic interests?
- Does the methodology of the study imply ethical concerns?
- Which skills are necessary to conduct the study?
- Does the researcher have the necessary skills to conduct the study and are there any necessary certifications needed (like for clinical trials)?
- How are the interests of the principle investigator balanced and are there any conflicts of interest?
- Will it be guaranteed that the involved supervisors are required to act in the students' best interest, and not to take advantage of their dependence with regard to professional findings as well as private lives?
- Are randomized branches of the study soundly balanced?
- Are there any legal or ethical approvals necessary before conducting the research?

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The sponsor's interest, reliability and influences are also of ethical importance to assess the study and the research process. Sponsors who are funding a certain study may have a huge influence on the ethically soundness of the study, its results and how the results will be shared. In particular, economic interests need to be demonstrated and balanced against other interests such as therapeutic goals, social goals etc. Commissioned research may also lead to conflicts of interest: When research is commissioned by an external funder, a number of conflicts may arise that affect the research or its communication. Explicit contracts between the funder and the institution conducting the research is therefore advised, enabling researchers carrying out the commission to abide by the research ethics guidelines.

Law and Legal Issues

The most obvious legal requirement to point out is the contractual nature of the relationship between the funder and the researcher (and the research institute). How far the contractual terms for a particular grant are negotiable differs between funders. However, it is worth remembering that, despite the power balance, it is a matter of negotiation.

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Therefore, the following aspects need to be considered:

- How reliable are funders or sponsors of a study and what are their central interests?
- Is there any other conflict of interest?
- Are the expenses of a study justifiable?
- What can a sponsor do to guarantee the ethical soundness of the study?
- Did the sponsor set up a specific code of conduct that has to be considered?

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Personal data generated in research projects may lead to important scientific findings with a high social impact but at the same time the use or misuse may result in individual disadvantages, stigmatisation or discrimination, i.e. in particular when the data is stored for a long time in a database or biobank. Therefore, every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information. In many research projects, and in particular in the publication of the results, national legal framework conditions and, in Europe, the General Data Protection Regulation (GDPR) must be taken into account. Certain research methods are subject to strict data protection requirements. Projects that generate sensitive personal data, in medical or psychological research, may also be subject to an assessment by an ethics committee.

When research involves the collection of personal data, researchers are expected to adhere to ethical standards as recommended by professional panels, institutions and funding organisations, both during research and when sharing data. Sensitive, personal and otherwise confidential research data can also be shared ethically and legally if the ethical aspects are considered at the beginning of the research and informed consent has been obtained. All users must carefully consider common actions. In particular, in the case of funding applications, but also before publication in international journals, in some cases a review by an ethics committee must be kept in the records.

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Therefore, the following aspects need to be considered:

- What are the ethical considerations with regard to the data collection in the study?
- Is the data taken from previous studies or data banks?
- Does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?
- What are the ethical concerns with regard to processing and mapping genetic information?
- Are persons being tracked or observed in the study?
- Does this research involve further processing of previously collected personal data (secondary use)?
- Are the purposes of the use of data negotiated with the human participants?
- How is the identity of the research persons protected (anonymisation, pseudonymisation)?
- Who has access to the coded data?
- Is an ethical approval necessary?

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The main objectives of medical research involving human participants is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven methods must be evaluated constantly through research with regard to their safety, effectiveness, side effects, accessibility and quality. Life and health of the patient or the healthy volunteers are the centre of all acts in biomedical research. The researcher must be qualified to conduct the research and needs to hold up to date certificates for medical research. In case of patients as research subjects, the double role of those who conduct the research as researchers and medical doctors may violate the appropriate attitude towards the person in question because research goals and interests differ from the mere acquisition of scientific knowledge. In biomedical research with human participants, the researchers need to respect the principles of non-maleficence and beneficence. Any medical interventions are only allowed after informing the participant comprehensively about goals, methods, risks and burdens in the study and obtaining informed consent. It has to be considered that not only physical interventions can harm, but also the spoken word and non-physical interventions like interviews, questionnaires or surveys.

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Therefore, the following aspects need to be considered:

- Are there physical interventions included?
- How intensive is the invasiveness (injections with new substances (drugs), blood samples, radiological interventions, devices etc.)?
- How intensive are the non-physical interventions (i.e. interviews, questionnaires (life style, psychological states, behaviour, sexual practices and preferences))?
- Is there any physical or mental stress/burden expected?
- How do the expected risks look like?
- Will human tissue, body liquids be collected or used?
- Will biomaterials be stored in biobanks?
- Are the experiments physically or/and mentally demanding?
- Will placebos be used?
- How will participants be informed about the possibility of incidental findings and how will incidental findings be communicated?
- Are the participants covered by an insurance?
- In case of patients as research subjects: How will the researchers deal with their double role as doctors and researchers?

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Respect of the person continues with the rights concerning the use of the human body and its parts. Human body materials cannot only be considered as mere research subjects, but at the same time as related to a human person. Therefore, the use of human body materials also requires justification by the human subject that has donated the biomaterials.

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Therefore, the following aspects need to be considered:

- Is the human tissue obtained in the study?
- Is the human tissue commercially available or imported from another lab or biobank?
- Is there informed consent that allows the removal and use of body material?
- Is it clarified for which purposes the body material may be used?
- What if other than the indicated purposes occur during the study?
- May the body material be stored in biobanks for further research?

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There is widespread agreement that the goals pursued in research involving human embryonic stem cells (hESC), both in fields of basic biological research and therapeutic research, are not only legitimate, but also eminent, i.e. “high-ranking”. But opinions differ, however, on the question of the justifiability of the means used in this research, if they involve the utilisation and - according to state-of-the-art technology - also the destruction of human embryos. In various countries, the use and destruction of embryos for research purposes is strictly prohibited. Furthermore, the use of fetal tissues and cells is not harmonised in the EU. The legislation in EU member states concerning research with embryonic stem cells, embryos, fetal tissues differ very much and need to be carefully considered in particular, if the research is conducted cross-nationally.

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Therefore, the following aspects need to be considered:

- Are hESC directly derived?
- Are the hESC previously established or imported?
- Does the study envisage the use or destruction of human embryos or the use of embryonic/fetal tissues?
- Is the study in compliance with the relevant national regulations?
- Is there an ethical approval to use embryonic or fetal tissue?

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From an ethical perspective, biobanks are, on the one hand, high-quality resources for internationally networked research that feels committed to high-ranking health and research goals conducive to the common good. On the other hand, biobanks are a sensitive source of personal data whose use is susceptible to abuse. An individual approval solution and the goal of a comprehensive benefit for the common good may conflict concerning certain proceedings and normative assessments. For an ethical evaluation, it will be decisive to what extent the individual feels or can be obliged to the common good and which efforts a community undertakes to protect individual or group-based rights and interests and not inappropriately sacrifice them to the common good. For biomedical research using identifiable human biomaterial or human data that is stored in biobanks or similar repositories, researchers must seek informed consent for its collection, storage and/or reuse. There may be some exceptional situations where consent would be impossible or not practicable to obtain. In situations like this, the research may be only conducted after a review and approval of a competent REC.

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Therefore, the following aspects need to be considered:

- How does the structure and governance of biobanks (managed by a board of trustees, ethics committee involved, informed consent procedure within the database) look?
- Does an ethics committee council the biobank?
- How is the informed consent derivated?
- Does the informed consent include the use of data and materials beyond the study?

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In psychological research, a variety of methods is used. But also, non-interventional studies may harm the participants, like interviews or questionnaires with sensitive topics and questions. In particular, when a study design includes deceptions or illusions, a complete information cannot be given by the researcher for systematic reasons. This procedure needs very careful considerations. Historically, there are very negative experiences in particular with the long-term harm of the participants (i.e. Milgram-Experiment, Stanford-Prison-Experiment). Since the spoken word can harm as the scalpel of the surgeon, the risks and burdens for research participants have to be carefully considered. This is of particular importance when the participants belong to a vulnerable group (i.e. children, traumatized migrants).

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Therefore, the following aspects need to be considered:

- How does the design of studies and interviews look like and does it imply ethical aspects?
- How sensitive are the questions?
- How does the study design deal with elements of deception/illusion and informed consent?
- How intensive are the non-physical interventions (i.e. interviews, questionnaires (life style, psychological states, behaviour, sexual practices and preferences))?
- Is there any physical or mental stress/burden expected?
- Are vulnerable people involved (minors, traumatized persons, disabled persons etc.)?
- Are all data protection aspects considered?

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Qualitative methods like interviews, observations and participant observations require face-to-face interactions with humans, which may cause mental strain or unnecessary burden to participants. Respect for human dignity, personal integrity and privacy is essential, as also stated in international human rights laws and conventions. Additionally, possible social, organizational, cultural or political consequences of the research should be considered, especially the protection of vulnerable groups. Central ethical issues and principles include assuring anonymity and confidentiality, ensuring that participants are not exposed to physical harm or unreasonable strain (especially in research on sensitive issues), consideration of effects on third parties, respect for privacy and family life and providing the participants with adequate information on the research and its intended use of results. A particular ethical challenge in observation studies is the admissibility of hidden forms of observation (covert research).

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Therefore, the following aspects need to be considered:

- Is there an approval given by a REC?
- How will anonymity and confidentiality be ensured?
- How will informed consent be ensured? Are the participants able to give informed consent?
- Is information given in a neutral manner, not exposing subjects to undue pressure?
- Are the possible mental strains for participants?
- Are questions framed with attention to ensuring respect and dignity towards participants?
- Are the questions / topics sensitive to cultural backgrounds?
- Could third parties, who are not part of the research, be affected?
- Is the information provided to participants clear with regards to expected outcomes, avoiding unreasonable expectations?
- Are hidden observations / covert research anticipated, and if yes, does the utility value of the research exceed disadvantages for the individuals involved?

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In the technical disciplines and engineering sciences, there are questions of RE with regard to the transfer of methods and products to industrial applications, questions about their general social consequences, but also questions about the long-term potential of side effects on the environment and on society (cf. areas such as energy, digitalisation are very sensitive). When it comes to devices and applications that are used directly on humans (cf. machine-brain-interfaces), special precautions must be taken and the research participants must be carefully informed before they may give their consent. From an ethical point of view, particular ethical attention must be paid to this area, as there are only a few uniform guidelines or laws outside the sector of the development of medical devices.

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Therefore, the following aspects need to be considered:

- Will the developed technical devices have a direct interaction with human beings (machine-brain-interfaces, implementations etc.)?
- What kind of social implications does the technology have that will be developed in the study?
- Are long term social and environmental effects and side effects considered?
- Is there a need for ethical approval?
- Are the implications of the industrial application of a developed technology ethically considered?
- Are aspects of secondary or dual use considered?

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In environmental research, like e.g. research on climate change or ecology, possible risks of harm to the environment, flora, fauna, but also to human beings (the concept of one-health) need to be considered. There are three primary but inter-related principles with ethical foundations which guide the reflection on such research: the Principle of Sustainability, the Precautionary Principle, and the Equity Principle in relation to future generations. Secondary to these are e.g. the conservation of biodiversity and Responsible Research and Innovation (RRI). When people live in the area where the research will take place, the interests of the people also have to be taken into account, adhering to RRI. This is especially important when indigenous groups are concerned. When research will deal with endangered flora, fauna or protected areas, or ecological impacts on them, the precautionary principle should be employed and possible risks should be assessed. For assessing possible consequences for environment, animals and humans, applying an ethical matrix could be useful.

The principle of sustainability is normally portrayed as comprising three inter-related aspects: nature, economics, and society / culture. The protection goals of each of them are clearly value-based, as are their indicators. Sustainability as a normative commitment is a moving-target, and there is no single silver-bullet to complete this ideal.

The Precautionary Principle (PP) is much debated in the literature, with criticisms in particular from the US/North-American side. It gained most prominence in the Rio-Declaration, and has now a renewed importance through the UN Sustainable Development Goals (SDG) of the UN. In the EU, the PP entered the Nice Treaties of 2000. Definitions of the Precautionary Principle vary in different treaties and different legal regulations. Instead of being based on negative characteristics (in the Rio Declaration a triple negative statement: not having sufficient knowledge is not a reason for not acting!), the UNESCO adopted a positive formulation in 2005: “When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.”

The principle of intergenerational equity or rights of future generations is not clearly defined anywhere, but it is alluded to in many formulations of sustainable development as the part relating to the human dimensions. It emerged clearly in the work of the Brundtland Commission: meeting the needs of the present without compromising the ability of future generations to meet their needs.

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Therefore, the following aspects need to be considered:

- Does this research involve the use of elements that may cause harm to the environment, to animals or plants?
- Does this research deal with endangered flora and/or fauna/protected areas?
- Does the research involve and clarify large system uncertainties which should be communicated for policy, and suggest a precautionary approach in practice?
- Are there any culturally or socially controversial or sensitive impacts (culturally sacred places or monuments, privacy, property rights, rights of indigenous groups)?
- Are aspects of access and benefit sharing carefully considered?
- Does the research have an international impact and may conflict with international regulations?
- Are all data protection aspects considered?

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The term „integrity“ originally refers to something, or even a collection of things, as being undisturbed from later interferences. It has become a moral concept when applied to humans, and when we ascribe integrity to someone we normally imply that this person acts according to an undisturbed moral standard. This is often related to virtue ethics. But in recent years the integrity of nature has become a prime concern in academic and public discussions on the ethics of for instance genetic engineering and more generally on our use of natural resources. It is not often explained in detail what the term means in these contexts, but the monitoring of induced changes in key ecological systems, measured by various indicators, is one of the contexts where one seeks to maintain ecological integrity. In animal and livestock care some resemblance to the natural living conditions of the animal is also described as maintaining their integrity. In this manner the integrity of nature has become a major concern in bio- and environmental ethics. In some countries (some aspects of) the integrity of nature or the living ecosystem has entered environmental laws.

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Therefore, the following aspects need to be considered:

- Does the research have a negative impact on the integrity of the ecosystem or the animal's natural living conditions?
- To the extent that such research seems necessary, are there any interventions or alternatives with less harm to the integrity of nature?

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Animal suffering should be avoided in research and the number of animals needs to be reduced by alternative settings such as research with tissues or computer stimulations. If this is not possible the 3Rs should be respected. Good scientific practice and appropriate animal welfare go hand in hand. Suffering stress or pain of an animal may affect the study design and the findings of the research. Therefore, good housing conditions of animals are scientifically and ethically necessary. It should be guaranteed that the treatment of animals will only be conducted by skilled and experienced caregivers, who are aware of the needs of animals. When a researcher plans a study, he must demonstrate that there is no alternative method not involving the use of animals. The three Rs have to be carefully considered in the design of the study:

- Replace the use of animals with alternative methods or avoid the use of animals altogether.
- Reduce the number of animals used to a minimum, to obtain information from fewer animals or more information from the same number of animals.
- Refine the way experiments are carried out, to make sure animals suffer as little as possible. This includes better housing and improvements to procedures which minimize pain and suffering and/or improve animal welfare.

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Therefore, the following aspects need to be considered:

- Are the three Rs carefully considered?
- Are there alternatives like cell lines, tissue samples or simulations?
- What are the numbers of used animals?
- What animals are used?
  - Vertebrates
  - Primates
  - Genetically modified organisms/Crispr-Cas modified organisms
  - Cloned animals
  - Wild animals
  - Endangered species
- Is the housing of animals conducted by skilled specialists?

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The quality of research is one of the major ethical concerns for all research. The notion of quality can here be read as being fit-for-purpose. Research can have all kind of purposes and functions (as explained in the introduction), and therefore the important point is that the research is presented in a way that meets the particular functions for which it is designed. In science for policy, but also in many other uses, the clear delineation between what one knows and what one does not know is an important characteristic of quality. If a policy maker is to base a policy on scientific advice, it is important for her to be able to assess the uncertainties as well. As one has also come to realise that facts and values often are inherently intertwined, even in the best of research, one should make an effort to elucidate the value assumptions which enter the research and guide the applications. As a result, the explicit inclusion of dimensions of uncertainty and value assumptions should be a routine consideration in research. The same holds true for values.

Researchers have nowadays many ways to address uncertainties and values in their research. The methods go beyond standard statistical error margins, Bayesian likelihood approaches, Monte Carlo analysis, and sensitivity analysis. The literature points to the multi-dimensionality of scientific uncertainty, and suggest means how to perform a knowledge quality assessment. One such scheme is the NUSAP scheme.

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Therefore, the following aspects need to be considered:

- Are the uncertainties accompanying the research made explicit in a comprehensible and comprehensive manner?
- What are the implicit value assumptions in the risk analysis, the problem framing, the models, and the data selection?
- Were the reasons for choosing and studying the system obvious and justified in relation to related systems or to alternative demarcations of the system?
- If the subject matter is a complex system, is the scaling of the system adequate for the purpose it is to serve?

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LITERATURE

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- More on the topic on these websites: http://www.nusap.net/ and https://en.wikipedia.org/wiki/NUSAP

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Big data and internet-based research technologies provide many possibilities for research, but it also comes with new research ethical dilemmas regarding e.g. informed consent, privacy and anonymity. Even if something has been shared publicly on the internet, it does not mean any subsequent use is unproblematic, or that the data creators consent to researchers using their data. Further, as big numbers of data often give impressions of solid data, limitations and weaknesses of the data and the analysis should be clearly communicated, including articulating what the data or the indicators represent. Researchers should be sensitive to the potential multiple meanings of data.

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Therefore, the following aspects need to be considered:

- Is the data sufficiently anonymised?
- Are the possible harms, breaches of privacy and possibilities for consent assessed?
- What are the limitations of the datasets, the analysis methods and the interpretations?

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Scientific publications are one of the central principles of good scientific practice. The results of a study should be shared in the scientific community. It is necessary to provide the results for further scientific discussions. In particular, falsifications should also be published (i.e. when a substance does not have a therapeutic effect as proposed) because this will lead to less useless studies of this kind. Additionally, there is an ethical value to inform the public about central scientific results as well, in particular when it is of specific societal relevance.

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Therefore, the following aspects need to be considered:

- How will the findings be published (scientific community and public)?
- Does the dissemination of the findings include didactically sound mechanisms to inform the public?
- Will the results be published with open access?
- Does the publication meet all requirements of good scientific practice (validity, authorship, data management etc.)?
- How will the scientific community be informed about the falsification of a research hypothesis?

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Scientific outcomes need to be validated in a scientific peer community in order to be trusted by users. Ever since the Scientific Revolution, the mechanism for this has been, and still is, the peer review in scientific publications. However, in recent years it has been recognized that this is not always good enough. Issues like inadequate statistics, the non-reproducibility of many research papers, p-hacking, and some others have led to a heightened awareness of better and more comprehensive mechanisms for quality assurance of scientific outcomes.

Pathbreaking for this discussion was the research of John Ioannidis, a Stanford statistician. It showed shocking shortcomings in the quality of published research which undermined their utility for further research and use. The reaction has been that the sciences publish too much too quickly, probably because of commodification of the scientific enterprise. The remedy must be a revised and extended mechanism for quality assurance. This task should foremost be anchored in the research groups themselves, and built upon critical evaluation of methods and results before publication.

The post-normal science tradition, initiated by Silvio Funtowicz and Jerome Ravetz, has focused on the fact that in science for policy system uncertainties are high, facts are debated, values in dispute, and decisions are urgent. This leads to facts and values being closely intertwined, and thus the problem arises that quality assurance by scientific experts alone might not be adequate. They call, therefore, for extended peer reviews as a mechanism for quality assurance, including end-users, stakeholders and citizens at large.
In terms of ethics, it is the overall scientific quality that influences the trust people can put in science. Betraying that trust through poor research results inflicts damage on the scientific enterprise and its role in society.

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The following aspects need to be considered:

- Are the planned quality checks of the research sufficient to secure a robust outcome of scientific results?
- Does the statistical research comply with the ethical guidelines for the use of statistics?
- Has the research a complexity and scope that would indicate an extended peer-review by end-users, stakeholders and / or citizens at large?

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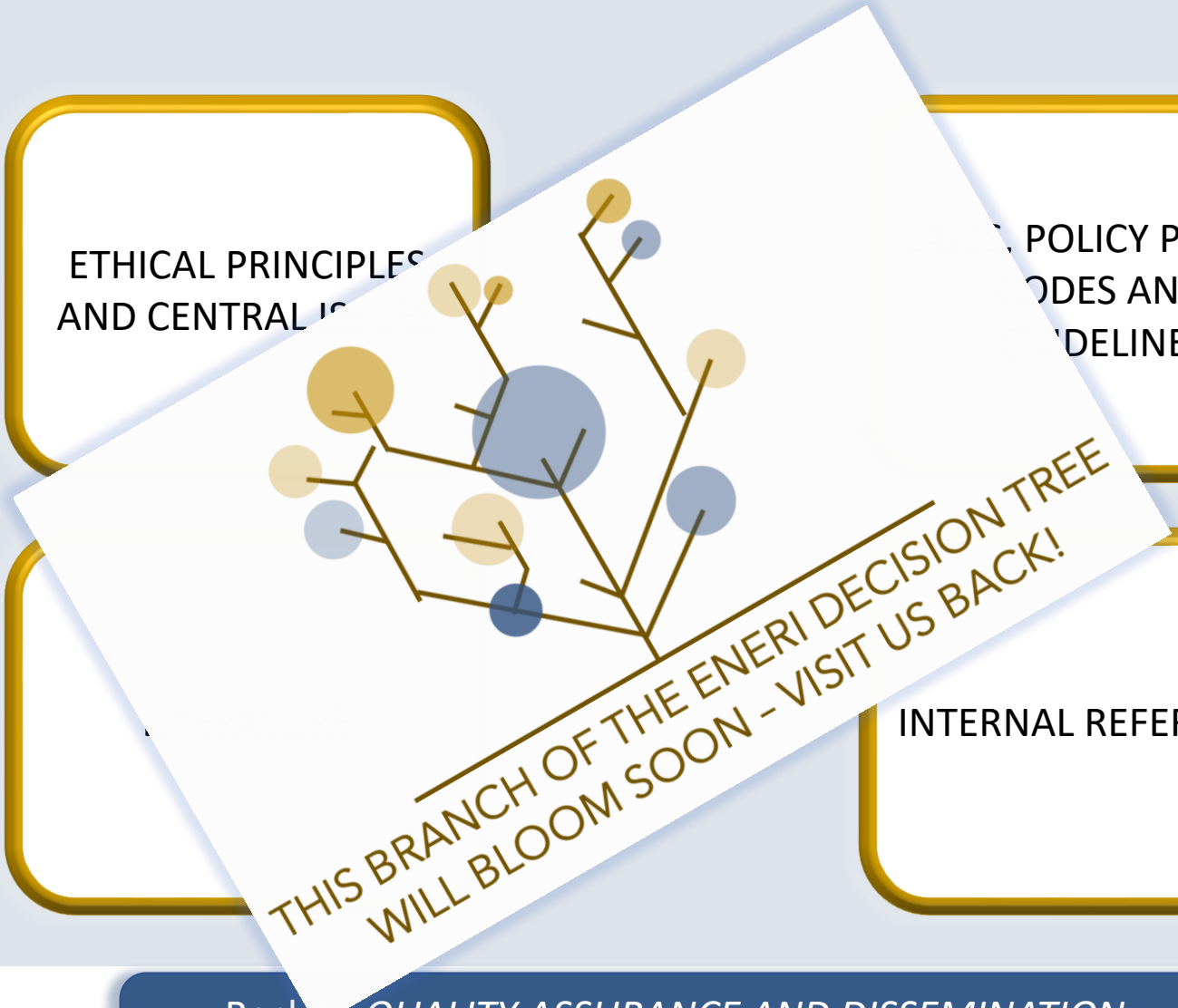

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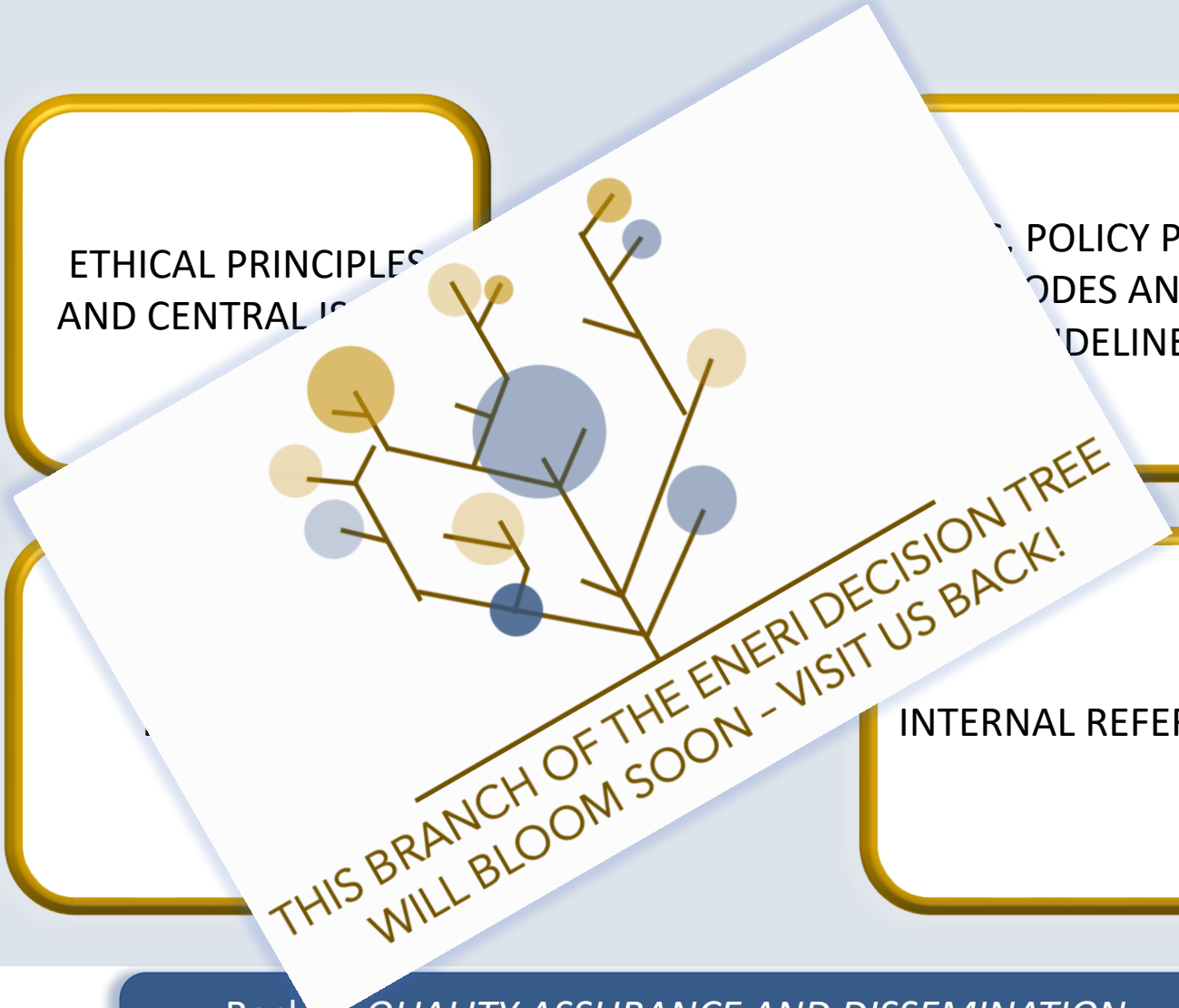

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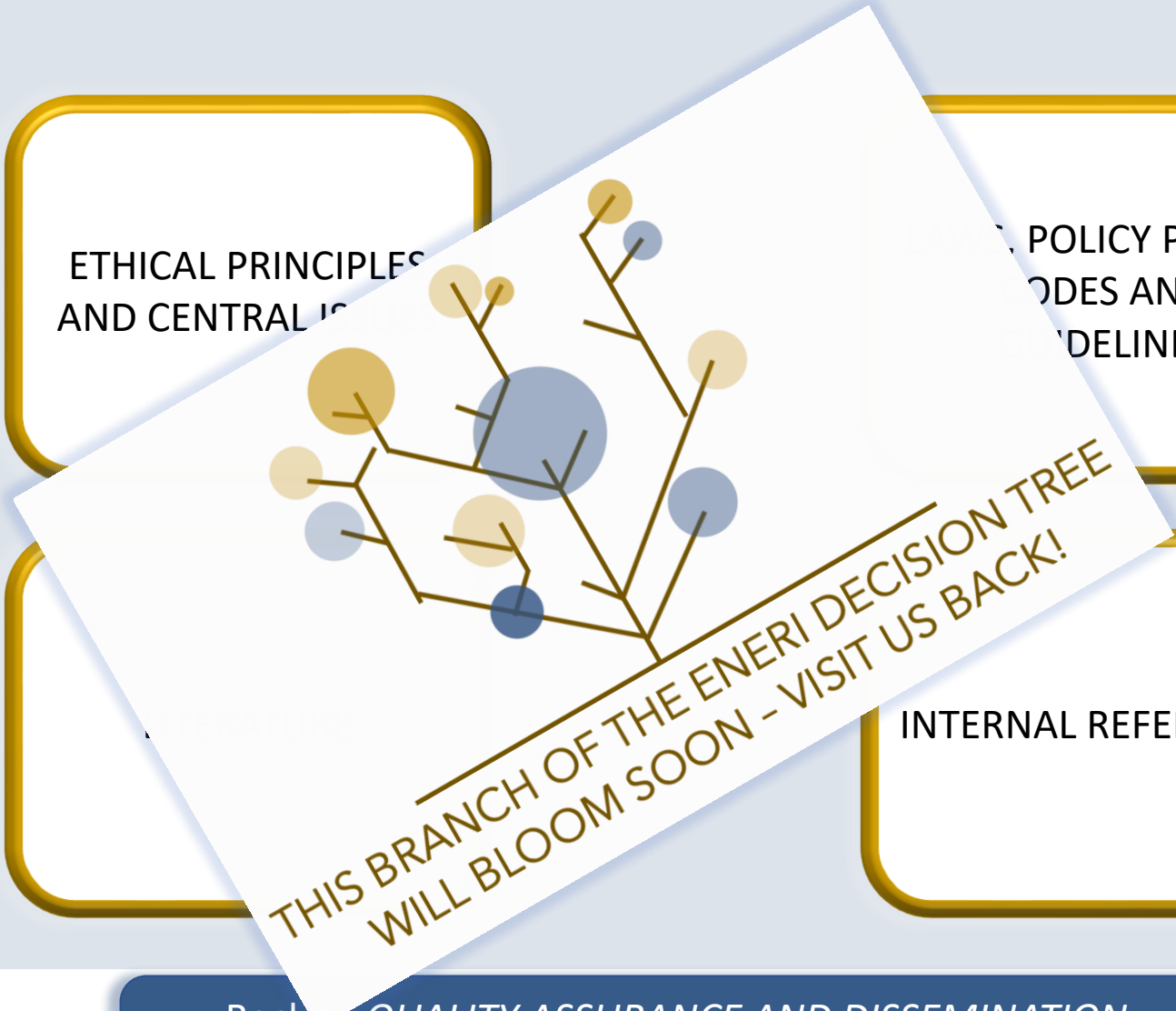

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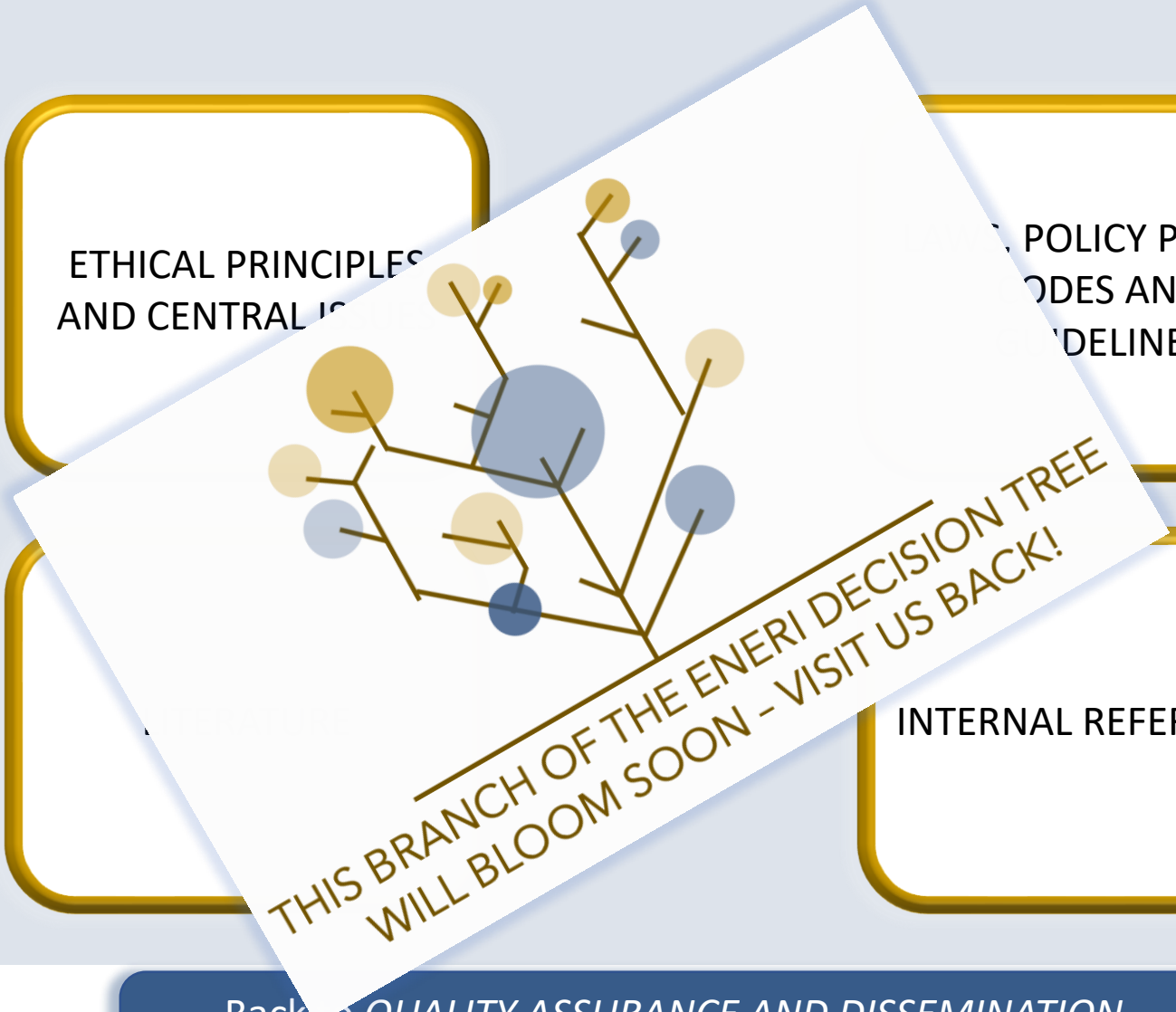

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A study may develop a technology that is normally used for civilian purposes, but might be ready for dual use, i.e. this technology can also be used for military and criminal ends. More generally speaking, dual use technologies may satisfy more than one goal at any given time. The most dramatic example of dual use in the history of science often referred to is the making and use of the first atomic weapons. There are, however, several examples in other and also more recent fields like biotechnology and medicine. For instance, there were debates which showed the vulnerability of public water supply, and it was argued that these same studies – intended to improve the system - could also be seen as a blueprint for terrorist attacks on public water supply. Widely discussed in this connection is genomic research on bacteria or micro-organisms. The fact that small changes in the genome by means which are largely publicly available can create both vaccines and pests which could be used by military forces or terrorists causes serious concern.

The researchers should consider the ethical consequences of dual use. Not only hardware technology can slip into the dual use problematic, but also arithmetical items like specific elements of software or algorithms.

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The following aspects need to be considered:

- Do the developed technologies (i.e. hardware, software, algorithms) include options for military use?
- Do the developed technologies (i.e. hardware, software, algorithms) include options for criminal or terrorist purposes?
- Are there any mechanisms included in the research design to avoid the misuse of the developed tools?
- Could the research results harm people?
- Could the research results be used in another way than intended?
- What kind of societal consultation is advisable in order to hear multiple voices on the benefit-harm balance, and views on the research as such?

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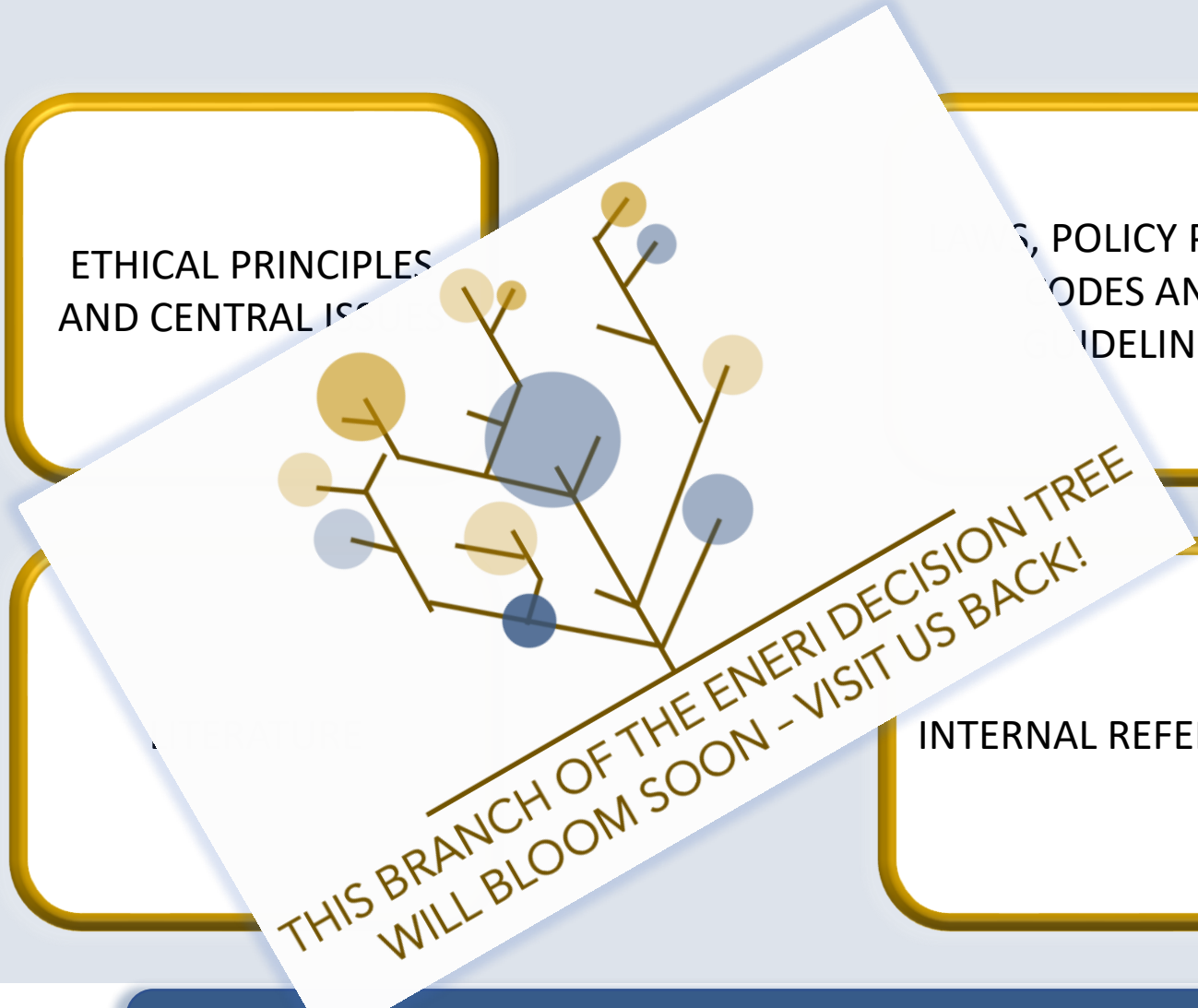

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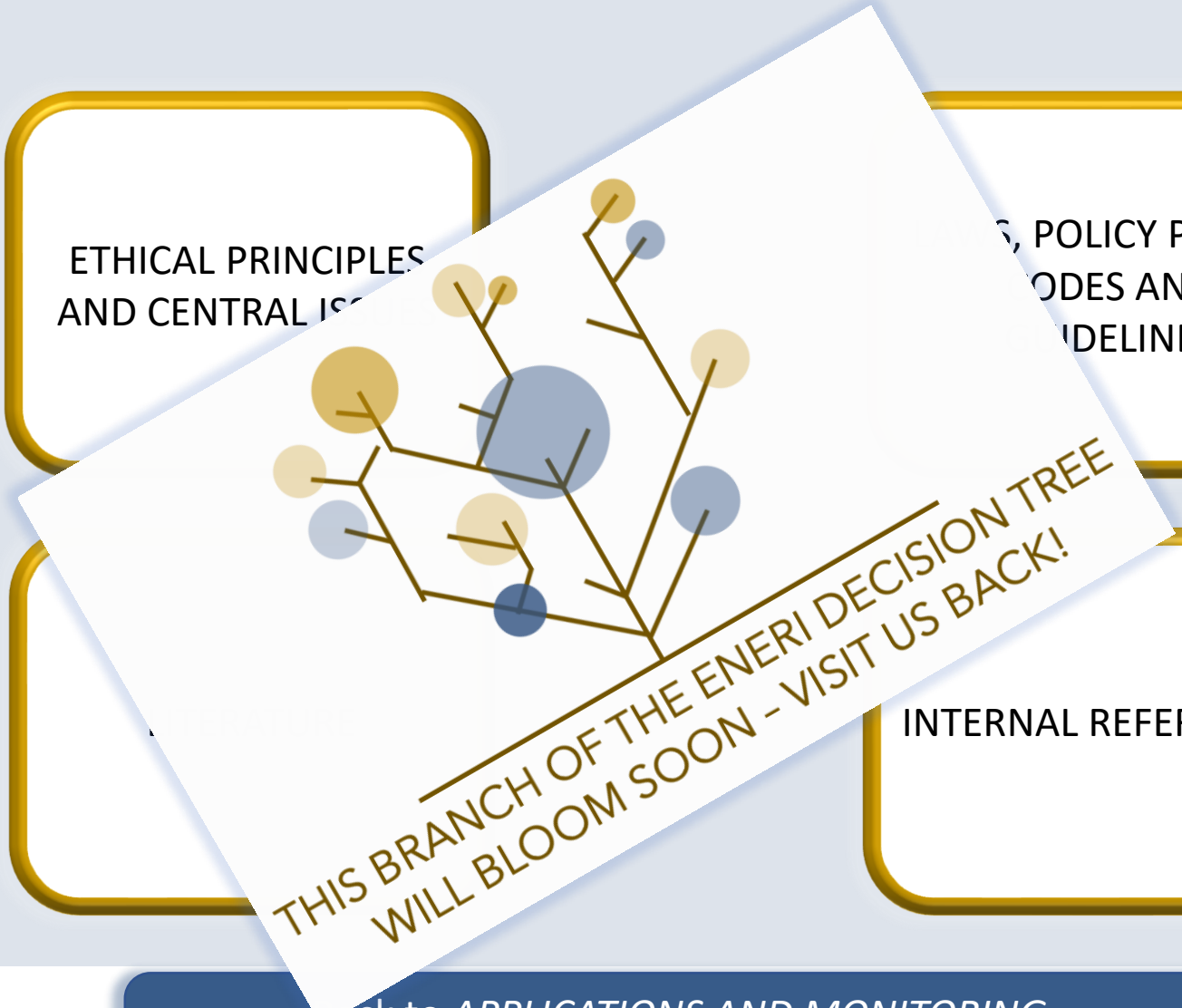

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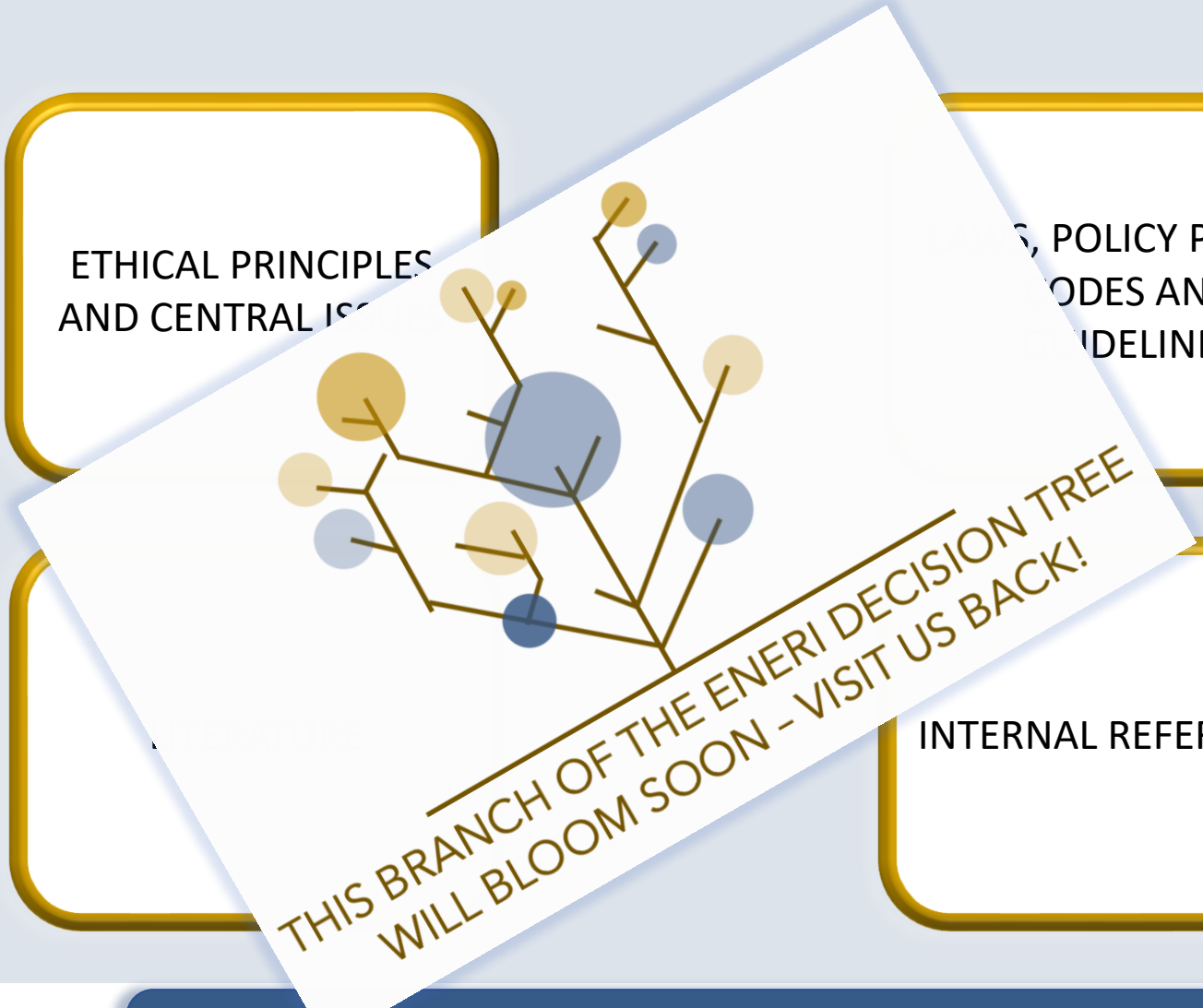

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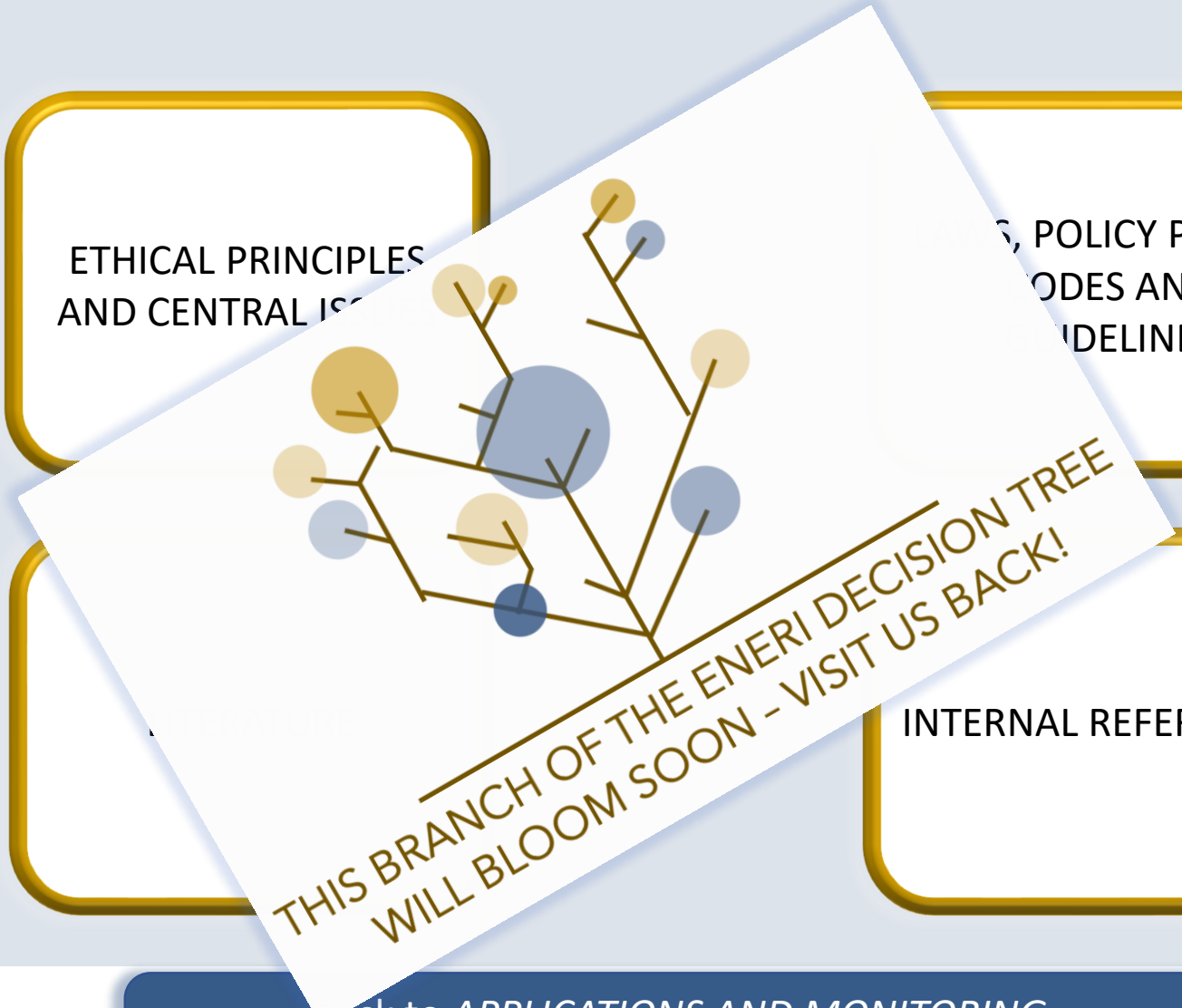

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