Guide for in-depth ethical reflection for research projects

Preface

Engaging in ethical reflection means reflecting (ideally with others or in a multidisciplinary fashion) on one's actions, their consequences, and the underlying values and principles. In the context of research projects, this process means reflecting on a project's objectives, the means used to achieve these objectives, and the project's consequences. It involves verifying that, even if the project can help advance knowledge or even societal development, the work will not detrimentally affect individuals, groups, organisations, or countries...as well as living species (non-humans) or the environment. In this process, ensuring legal compliance is a prerequisite as it establishes a framework for practices and imposes limits. However, legal compliance is not the core of the process, as the law cannot cover or regulate all our actions; indeed, only certain topics, sometimes because of abuses or growing societal pressure, have become subject to regulation. Furthermore, ethical reflection is not the simple enumeration of principles and shared theoretical values. Instead, it also raises questions about how these principles and values are put into practice during a specific project.

This self-assessment guide was designed to help you with this complex process. Ethical reflection involves a critical analysis of the project's objectives, your own motivations and those of your partners, the methods employed, and the associated risks. You can engage in ethical reflection whether you are a project coordinator or simply a project partner. It must be undertaken before the project begins and should continue throughout its implementation.

You are encouraged to consider the most appropriate choices for your specific context using collective and personal value scales; it is also important to distinguish between what is feasible and what is ethically acceptable, putting yourself in the place of study participants considering things from the perspective of participants, your research partners, and future generations while also respecting living species and the environment. This guide also addresses many regulatory issues that are linked to ethical reflection. More specifically, this self-assessment can help you identify the regulations with which you must comply and invites you to explore these issues in greater depth to ensure that you are in legal compliance[1,2]. Ethical reflection must not be reduced to a list of boxes to check. This guide contains many open-ended questions that should be discussed with others, such as your project partners or your local work group (team or unit), for example. You should take as much time as needed to identify the relevant questions, reflect on them, and, if necessary, modify your project accordingly.

[1] The self-assessment provides links (to resource information and people at INRAE), including some that can only be accessed via the INRAE intranet. You will therefore need an LDAP identifier, which is available to all INRAE employees and members of INRAE joint research units upon request to your unit's HR manager. These links are in **turquoise**.
[2] See **Victor**, INRAE's monitoring tool dedicated to regulated scientific activities and the **DAJ intranet**.

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I. Project objectives

Before embarking on any in-depth reflection around respect for people, the environment, and living organisms via an analysis of the project's methods and consequences, it is important to broadly explore your motivations and the project's scientific and/or societal end goals. First and foremost, you must assess whether there is alignment with fundamental ethical principles as well as the values important to you and your community. These questions will be explored in greater detail in the sections below, but it is essential to address them from the start of your reflection process.

- What is the project's objective? What motivates you and your team? Are your personal goals compatible with the project's goals?
- Do these objectives and motivations align with ethical principles affirming respect for individual autonomy, beneficence, non-maleficence, and justice?
- Are the project's objectives consistent with the no-harm principle regarding individuals, communities, and society as a whole?
- Are the project's objectives compatible with respect for animal welfare and the preservation of the environment and biodiversity?

II. Project partners and stakeholders

Reflecting on the relationships among partners is an important step in the ethical analysis of a project. It is necessary to consider the co-construction process, compatibility in objectives and motivations, and results sharing. Indeed, these issues must become the object of ethical reflection, considering the values of all project partners, whether they are private firms, non-profit organisations, members of the public, research institutes or universities and whether they are French or foreign. This work means acknowledging diversity in motivations and values while also respecting shared ethical principles and acting with transparency.

A. Partners (public institutes, private firms, non-profit organisations, citizens, etc.)

In this section, you are invited to think critically about the relevance of the partnership, the motivations of each partner, and the reality of sharing. The following questions will help you identify key points in this reflection process. Consider expanding your perspective and engaging your partners in the reflection process.

- What is the project's degree of co-construction? Is each partner transparent about their motivations, objectives, and methodological choices? How were the partners chosen?
- Is there compatibility in partners' objectives?
- What are the relevant interests of each partner? Can you identify any potential conflicts of interest?[3]

When in doubt, reach out to INRAE's code of conduct adviser (referent-deontologue@inrae.fr), who can help you identify potential conflicts of interest along with appropriate management measures.

[3] A conflict of interest is defined as *"any situation of interference between a public interest and public or private interests that is likely to influence or appear to influence the independent, impartial, and objective exercise of a function"* (French Law no. 2013-907 of October 11, 2013 on transparency in public life, Article 2).

- Will it be necessary to define (and implement) certain actions to ensure that all participants understand the project's objectives and impacts?
- What are the project's financial management rules? How will the project's means, resources, and benefits be shared?
- Who will benefit from the project? Could there be exploitation by one of the partners or could one of the partners be exploited ("greenwashing", "ethics washing", or exploitation of scientists or citizens, for example)?
- Are there terms and conditions regarding the use, publication, or communication of the results (including respect for confidentiality in certain cases)? Are these terms and conditions made explicit, understood, and approved by all partners?
- Could the partnership agreements (directly or indirectly) allow the project's results and/or biological materials to be used for purposes that are incompatible with the INRAE Code of Conduct, Scientific Integrity, and Ethics Charter, the recommendations issued by the Ethics in Common Committee, or your personal values?

See the INRAE Ethics, Scientific integrity, and Code of Conduct Charter and the website Ethics in Common | INRAE-Cirad-Ifremer-IRD.

B. States and local communities

In this section, you are invited to verify that your project will not cause harm to a foreign country or a local community. In particular, you must verify that the project complies with international law, local law, and French law (a project cannot be conducted abroad to circumvent French law).

- Will foreign countries and/or local communities be involved in the project?

This "involvement" can range from a research site abroad to a partnership with a foreign organisation. In France, do not forget about the special legislation that applies to communities of inhabitants in Wallis and Futuna and French Guiana (notably the access and benefit-sharing [ABS] agreement).

- If so, is the project compatible with local culture, values, and law? Have you taken care to respect the sovereignty of nation-states and the rights of local communities? Can you provide further details?

Failure to respect national sovereignty and the rights of local communities renders the project illegal.

- Are local partners substantially involved in building the project (see part IIA above)?
- Is the research being conducted in these countries legal in France[4, 5]?

Not only must the proposed research be legal and ethically acceptable in the foreign country where it will take place, it must also be legal and ethically acceptable in France.

- Would the research being conducted abroad have to undergo an ethics review if it were carried out in France[3]?

If so, in accordance with the principle of double ethical review, the project must go through an ethics review in France and, if possible, in the relevant country.

[4] To answer these questions, see parts III and IV: Respect for human persons and Respect for the environment, biodiversity, and living beings (non-humans).
[5] See Victor, INRAE's monitoring tool dedicated to regulated scientific activities.

- Will personal data be collected or exchanged?

If so, the project must comply with the GDPR (see part III.A) and with national laws in the relevant country. Indeed, the GDPR and the national laws are cumulative.

- As part of the project, will you be collecting, using, or exchanging genetic resources[6] of animal, plant, or microbial origin, related traditional knowledge, or even sequencing data obtained from genetic resources (DSI)?

If so, the project will have to comply with the access and benefit-sharing agreement (ABS, also known as the Nagoya Protocol), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), or other international regulatory regimes (e.g., the Convention on International Trade in Endangered Species of Wild Fauna and Flora [CITES]). It is necessary to carry out the self-assessment provided by INRAE's ABS unit (see the Sharepoint for ABS at INRAE and the ITPGRFA).

III. Respect for human persons

The best-known domain of research ethics is focused on respect for human persons. It is based on four main principles: autonomy (respect for personal choices and opinions), beneficence (obligation to act for the well-being of others), non-maleficence (prohibition of harm), and justice (equity among individuals or proportionality in actions). The application of these principles must be verified when conducting research involving human participants (research in human health, human nutrition, the humanities, and the social sciences); projects involving non-human subjects (e.g., in agronomy or ecology) where human beings participate in surveys or take part in participatory science and research; and any project that could have more or less long-term consequences for humans or society.

This area of research is also among the most heavily regulated. Thus, the french Jardé Law (2012), which provides a framework for research involving human persons (RIPH), and the General Data Protection Regulation (GDPR : Homepage | CNIL), which is a European legal framework for the collection and processing of personal data, are two ways in which the ethical principles of respect for human persons have been codified in law. Making sure that your protocols respect these laws is a prerequisite for their use. It is also important to consider the project's potential impacts (positive or negative) on individuals and society, independent of the specific protocols.

A. Participation of human volunteers

- Are volunteers involved in any of the project's protocols?

If so, and even if the project is not legally required to follow specifications for projects conducting human health research (see III.C), it is advisable to have your project undergo review by an ethics advisory committee[7], as many publishers will ask whether a review was performed when your results are published. These reviews may even be required by certain funding agencies (in Europe in particular). The following questions in particular will help you identify the most sensitive situations.

[6] Pay attention to how different countries may define "genetic resources", which can include any materials of plant, animal, fungal, or microbial biological origin, whether or not they contain genetic information. When in doubt, it is advisable to adopt a broad definition of genetic resources, ranging from species to the products of metabolism.

[7] A research ethics committee, such as the CER, or INRAE's ethics committee for research projects, for example.

- Will the project involve vulnerable populations (minors, pregnant women, the elderly, people under guardianship, financially disadvantaged people, minorities, etc.)?
- Could participation in the project lead to fatigue or to physical or psychological risks beyond those of everyday life? Could chance discoveries be made as a result of their participation? What support will be provided in this case?
- Will participants receive clear and precise information that is adapted to their level of understanding[8], enabling them to grasp the full set of conditions associated with their participation (objectives, institutions and partners, possible risks, special requests, possibility of withdrawing, possibility of contacting the scientists, etc.)?

If "no", it is important to modify the information given to participants or to justify why the answer is no (with experimental arguments).

- Is there a relationship between the volunteers and the project leader(s)?

Pay attention to any relationships (e.g., hierarchical, professional, or familial) that could hinder free consent and complicate the collection of sensitive data. In particular, we advise against recruiting volunteers from among your colleagues at INRAE.

- How will volunteers be recruited? Will volunteers be compensated?

These questions must be considered even if recruitment is carried out by a service provider.

The question of compensation is sometimes problematic. In theory, compensation can be offered (unless the study involves minors) and is often expected as a way of compensating for a participant's time and travel. However, this compensation cannot be equated with remuneration. Conversely, in participatory research, questions could be raised around the voluntary efforts of participants relative to the work furnished.

B. Collection or use of personal data

- During the project or project coordination, will you be collecting, using, and/or reusing data that would allow people to be identified (directly or indirectly via cross-referencing: name, address, GPS coordinates, age, profession, etc.)?
- Will you be collecting and/or using data (from analysis results, the identification of living organisms of all kinds or of substances, etc.) that could be linked back to identifiable individuals (directly or indirectly via cross-referencing or use of a code)?
- Will you be collecting or using sensitive data (of a political, religious, sexual, health-related nature, etc.)?
- Will you be collecting or using photos, audio recordings, or video recordings in which people may appear (intentionally or unintentionally)?

*If you have answered "yes" to any of the previous questions, you must take steps to make your project GDPR compliant. For more information, please visit the **INRAE and Personal Data webpages** or contact your unit's data coordinator. In particular, the following points will be important to consider when working towards compliance:*

- What is the legal basis for collecting and storing personal data?
- What informational documents, participation agreements, and/or consent forms will be used?
- Do you have an IT system that adequately safeguards personal data?

[8] Consider the special cases where participants are children or people with cognitive disabilities.

- Have the people who will be handling personal data received training (or been familiarised) with the GDPR and IT security?

These questions must be considered even if personal data is collected by a service provider (in such cases, it is important to ensure that the service provider complies with the GDPR and to verify the contract clauses relating to GDPR compliance).

C. Biomedical objectives

- Will the project use human cells or samples (human biological samples [HBS]), including those from commercial sources?

If so, you must comply with regulations regarding the preparation and storage of materials derived from the human body. (cf. Codecoh et EPCH).

- Is the project's direct (or indirect) objective to gain a better understanding of how the human body functions (under normal or pathological conditions) or to test procedures or products with a view to diagnosing, treating, or preventing pathological conditions?
- If so, will volunteers fill out questionnaires, experience procedures, be given products, or have samples taken?

If so, the project must be assessed by an institutional review board (CPP) in accordance with regulations. See intranet page Research involving human persons-RIPH.

- Will personal data collected during another project be analysed?

If so, it may be necessary to apply for authorisation from CNIL or CESREES. In other cases, particularly when the project uses reference methodologies (MR04, etc.) that need not be submitted to CESREES, it is strongly recommended that the project be submitted to an ethics advisory committee such as the CER. To this end, it is important to contact INRAE's data protection officer (DPO) and/or the ethics of research projects adviser.

- Will the project carry out simple surveys (no procedures, samples taken, or products tested)?

Depending on the situation, the project must be assessed by a CPP or a CER. For guidance, you can use a tool from the CER Federation that can point you towards the appropriate ethics review body.

D. Development or use of artificial intelligence

- Will the project use artificial intelligence (AI) tools? Is the project's aim to develop tools using artificial intelligence for diagnostic or decision-making purposes?

If so, you should submit your project to the INRAE ethics committee for research projects, and you should respect the seven ethical requirements specified by European guidelines: 1) human agency and oversight, 2) technical robustness and safety, 3) privacy and data governance, 4) transparency, 5) diversity, non-discrimination, and fairness, 6) societal and environmental well-being, and 7) accountability. Note the importance of obtaining consent from people if an individual automated decision-making tool is created (see Ethics guidelines for trustworthy AI).

E. Broader reflection on the project's potential impacts on people and society

- Aside from reflection on the project's objectives and methods, do the project's foreseeable impacts (over the more or less long term) align with the ethical principles

of beneficence, non-malevolence, and respect for individual autonomy? What impact could the project have on society? To what extent does the project use or generate **dual-use goods** (DUGs)[9]? More generally, could the results obtained be misused for malicious purposes (dual-use research of concern)?

In this section, we invite you to reflect broadly on the project's possible consequences regarding respect for individuals and society. As a reminder, respect for autonomy, beneficence, non-maleficence, and justice must guide your thinking. You need to think ahead, considering the situation from the perspective of other people, verifying that their autonomy and integrity will be respected and analysing the benefits and risks for all individuals and for society. Do not hesitate to expand your perspective and carry out this reflection process with others to conduct a critical analysis of ~~your~~ convictions and certainties.

Dual-use goods and technologies are likely to be used for both civilian and military purposes and are therefore subject to specific regulations. If you are unsure, you must contact INRAE Security and Defence Officer (fsd@inrae.fr).

IV. Respect for the environment, biodiversity, and non-human living beings

Ethical reflection must also extend to respect for living organisms and the environment, which involves considering a project's objectives, methods, and direct or indirect consequences. Here again, the principles of beneficence, non-maleficence, and proportionality must be applied. This section contains a wide variety of questions that can be asked. For example, exploring the environmental impacts of research prompts reflection around the greenhouse gas (GHG) emissions and chemical (or plastic) impacts of our research; it also prompts reflection around respect for ecosystems, biodiversity, and even the genetic diversity of domesticated species. This category includes highly regulated activities such as animal experimentation, genetic modification, such as GMOs or genome editing, and the harvesting and exchange of genetic material. There are also many unregulated types of research that merit careful consideration.

A. Environmental impacts of the project

- Will you be harvesting or handling protected species? Will any sampling or experimentation take place in a protected natural habitat?

*If so, you must obtain administrative authorisation or an administrative declaration (see protected species and **Victor**, INRAE's monitoring tool dedicated to regulated scientific activities).*

- In the case of ecosystems research or sampling in nature, could the project have a negative effect (immediately or over the longer term) on the protection of nature? What will you do to limit this impact?
- Have you thought about the project's overall environmental footprint? What could you do to improve it?

[9] These are material goods, products, or techniques developed for civilian applications that could also be used for military purposes in weapons or defense systems: dual-use technologies are civil-military technologies. The division that monitors exports of dual-use goods at the French Ministry of Finance defines DUGs as "equipment - including technology, software, non-material or intangible know-how - that is likely to have both civilian and military uses or that may - wholly or partially - contribute to the development, production, handling, operation, maintenance, storage, detection, identification, or dissemination of weapons of mass destruction" (WMD - nuclear, biological, chemical, etc.).

- Will non-human living organisms (animals, plants, microorganisms...) be bred/cultivated/cultured/experimented upon? If they were to "escape", would they present a risk to the environment and biodiversity? What measures will be taken to prevent their spread outside the laboratory or field plots?

In particular:

- What is their biological risk class? Do you know which regulations may apply to them?
- Have you carried out a formal analysis of the risks associated with their use?
- Does someone participating in the project have expertise in biosafety or regulated scientific activities?

*For help with these questions, see the **webpages on Biosafety**, accessed via the INRAE intranet, and **Victor**, INRAE's monitoring tool dedicated to regulated scientific activities. If necessary, you can ask questions via **Ariane for Biosafety**.*

- As part of the project, will you be collecting, using, or exchanging genetic resources of animal, plant, or microbial origin, related traditional knowledge, or even sequencing data obtained from genetic resources (digital sequence information or DSI)?

*The access and benefit-sharing (ABS) scheme does not only apply to samples collected abroad. It is always necessary to carry out the self-assessment provided by INRAE's ABS unit (see **ABS self-assessment**).*

B. Animal use and welfare

- Does the project involve the use of live animals?

*Regardless of which animals are used, it is important to consider potential suffering and how to minimize it, even if the protocol is routinely used and long established. Moreover, depending on the situation (animal, stage of development, and protocol), animal experimentation regulations may apply (see **Animal experimentation at INRAE**).*

- Will vertebrates or cephalopods be used?

If yes, the research institution must be accredited and any associated requirements must be met.

If no, your project is not subject to regulations governing the use of animals in research (aside from special cases involving protected species and/or species that present a biological risk); however, there may be ethical and/or biosafety issues to consider.

- Will the animals (vertebrates or cephalopods) experience procedures or conditions that cause pain (including stress)?If so, the project must be reviewed by a CEEA (animal experimentation ethics committee) as part of applying for APAFiS authorisation (see the Ministry webpage).
- Is an animal welfare/animal experimentation/livestock farming officer involved in the project?
- Have the people who will be experimenting on animals during the project been trained in animal experimentation? Have these people taken part in the reflection around the protocol?
- Regardless of whether animal testing regulations are applicable (CEEA review), is the project likely to raise ethical questions regarding its objectives, methodologies, or the consequences for the animals?

Answering the above question requires a critical analysis of the project. What are the alternatives? Is respect shown to the animal as an individual? Is animal suffering taken into account and minimised? What implications might the project have for the future use of animals by humans? Etc.

If so, and there is no obligation to conduct a CEEA review, it is nonetheless advisable to request a review by the INRAE ethics committee for research projects.

C. Modifications of living organisms

- Regardless of the study organism (microorganism, animal, or plant) or methods (breeding/selection, mutagenesis, genetic engineering), will the project use techniques that could affect the genetic heritage or characteristics of the organisms used?

Depending on the specific methods and organisms, regulations may apply[10].

If genetic engineering techniques are used, facilities must be GMO-accredited, and you must obtain the requisite authorisations (which are dependent on the organisms and cultivation/rearing conditions).

- What type of organism is being used?
- What alternative methods could be used to achieve the same objective?
- Will you breed or create genome-edited livestock? Are there plans to conduct field trials with genome-edited plants (created by the unit or a partner)?

If so, in addition to obtaining regulatory authorisation, you must submit your project to the INRAE ethics committee for research projects before any funding is requested. The committee's opinion will be used by the INRAE management board when deciding whether or not to authorise the project[11].

- Will gain-of-function microorganisms be obtained or experimented upon?

If so, you should contact your research division to determine whether you must submit your project to the INRAE ethics committee for research projects.

- Does the project include synthetic biology methods? If so, has a biohazard analysis been carried out?

It is always advisable to submit the project to the INRAE ethics committee for research projects.

D. Broader reflection on the project's potential impacts on the environment

- Aside from reflection on the project's objectives (sections I and II) and methods (section IV), are the project's foreseeable impacts (over the more or less long term) aligned with the ethical principles of beneficence, non-malevolence, and respect for the environment, biodiversity, and living organisms?

In this section, we invite you to broadly reflect on the project's consequences for the environment and living organisms. In addition to considering issues around the protection of the environment, biodiversity, and animal welfare, it is important to expand your perspective. For example, you could consider the consequences for farming practices (methods used in crop and livestock farming) or the gene pool of both wild and domesticated species.

[10] See Victor, INRAE's monitoring tool dedicated to regulated scientific activities.
[11] See the two official stances taken by the management board in 2018 and 2020 (plant genome editing and animal genome editing).