Guidelines on FWO's ethics checklist

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Background

These guidelines are designed to help applicants of FWO funding fill in their ethics checklist. The checklist is designed to identify ethically sensitive issues within the study subject and/or proposed study approach. This serves as a first step to recognise and deal correctly with any ethics issues that may arise in the course of the project design, execution and/or from the scientific findings.

At any time during the project period, researchers must carefully consider ethics issues that may arise from their research topic, methodology and results. Be aware that ethics issues may arise in any area of research. Apart from the obvious example, the biomedical and health field, research topics and methodology in social sciences, ethnography, psychology, environmental studies, security research, etc. may involve the participation of research subjects, the collection of personal and sensitive data, have an international dimension, create risk for research participants, researchers and uninvolved third parties, etc. In addition, ethical concerns may arise from the results of your research, e.g. the potential for misuse or dual use, or the impact on environment, health, safety or human rights. In the case where new risks arise during the execution of the project, not covered by the initial application, additional ethics approval might be required.

Please keep in mind that the ethics authorisation procedure may take some time and that therefore you should submit your application for ethics authorisation to the local ethics committee well in time.

This document covers many of the ethics issues arising in research projects, but it is not exhaustive. Because science, society, and attitudes to ethics are all continuously changing, situations will arise that are not (yet) fully covered by the guide. Cases that are not covered here must therefore be treated with extra prudence throughout the whole research cycle.

Along with ethics rules, your research, methodology, resources and technology must, also comply at all times with all applicable European and (inter)national laws and regulations and relevant policies. In addition, they shall also act in accordance with responsible research practices as laid down in, amongst others, the European Code of Conduct for Research Integrity (ALLEA) and other deontological declarations and protocols. Your host research institution is your primary point of contact for advice on ethical questions. Your institution will be able to provide you with information appropriate to your specific needs, legal environment and relevant policies.

Overview FWO's ethics authorisation procedure

Application phase: ethics checklist

The application forms for all FWO funding programmes include a section titled 'Ethics'. This section, based on the ethics questionnaire of the EU Framework Programme for Research & Innovation, contains a questionnaire related to ethical aspects of the proposed research topic, methodology as well as potential applications.

As part of their project proposal, applicants must complete this ethics checklist in an honest, complete and correct way.
An affirmative answer to the questions marked with an asterisk triggers an absolute obligation to obtain ethics approval from the appropriate ethics committee, before initiating any of the research activities concerned. In many cases, this is a legal commitment.
In case questions without asterisks are ticked, other obligations may apply (e.g. institutional policies, journal's requests, etc.) and/or applicants are invited to reflect on ethical aspects that may relate to the subject, study approach and/or result's consequences and applications. Consider contacting your host research institution for advice and/or take appropriate precautions if necessary or desirable.

No ethical approval is required at this stage.

For project proposals with the intention of experimenting on non-human primates however, the ethical review process must at least have been initiated by the project application's deadline. In practice, this is evidenced by uploading either the ethical approval for the intended experiments, or the acknowledgement of receipt of your request for ethical advice by the Ethics Committee on Animal Testing together with your project proposal. In the exceptional case that experimental data is missing that enables the submission of an ethical application by the time of project submission, a substantive argumentation must be submitted instead, arguing as to why the ethical approval procedure cannot yet start. In any case, FWO must be in the possession of the ethical approval for performing research on non-human primates at the time of the rebuttal, or, if no rebuttal is foreseen in the procedure of the subsidy channel concerned at the latest 1 month before the start of the evaluation panels.

Review phase

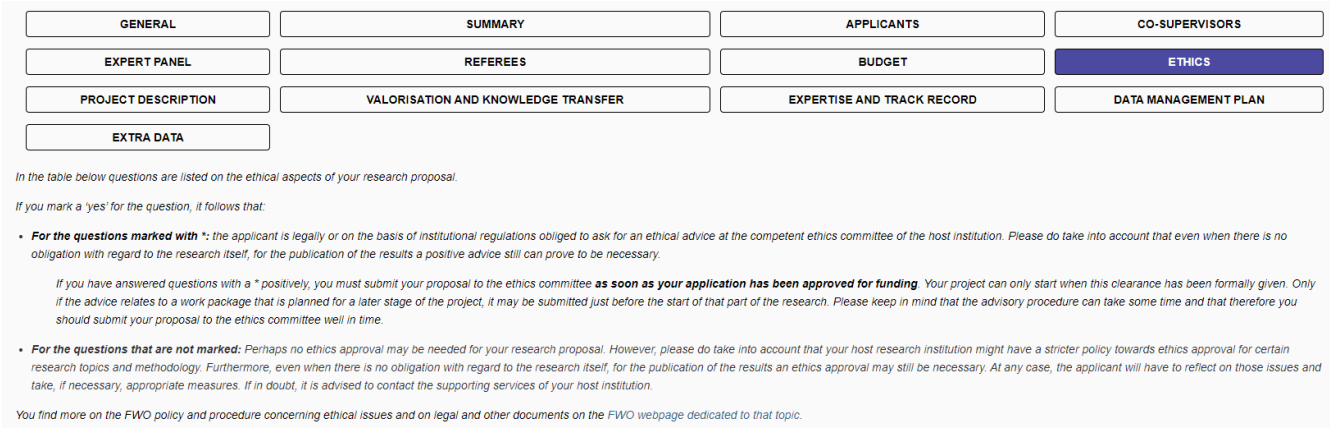
It is the researcher's responsibility to fill in this checklist complete and correct. The panel responsible for the evaluation of your application reviews the submitted ethics checklist and may indicate that ethical advice is required and/or formulate concerns, advice, preventive and/or corrective measures for specific ethical aspects.

Project execution phase

If funding is assigned to your project proposal, the completed ethics checklist (and possible addenda of the review panel) will at this point become part of your grant agreement with the FWO and therefore gives rise to binding obligations. Irrespective of whether it concerns a personal grant or a project subsidy, the beneficiary of FWO funding must now, for the aspects with asterisk, submit an application for ethics approval by the local ethics body that is responsible for overseeing the intended type of research (usually the relevant ethics committee organised by the host institution). For aspects not marked with an asterisk, other obligations may apply. For information about the ethics committees of the host research institution, the local procedure for requesting ethical advice, and guidance regarding the other ethics issues, you must contact the research coordination department of your host research institution.

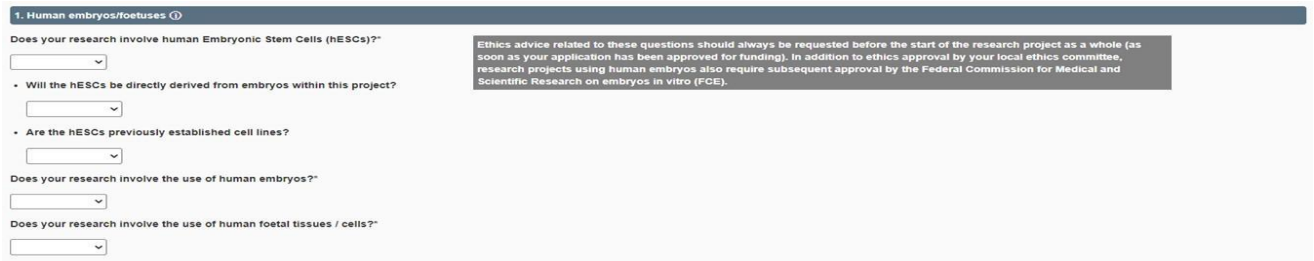
The FWO does not take an ethical position but follows the decision of the competent local ethics committee. The FWO or its assignees may request proof of the ethics approval *ad hoc* or during sample audits of projects. Approvals may be requested at any time during the project period and up to five years after the end of the project.

Ethics checklist



1. Human embryos, foetuses and human embryonic stem cells.

This section covers research on human embryos and foetuses, including human embryonic stem cells (hESCs).



Ethics checklist

Questioned research topic/methodology	Aspects to be considered
*Does your research involve human Embryonic Stem Cells **	
Will these be derived from embryos within the project?	• Origin of embryos • Recruitment, inclusion & exclusion criteria • Informed consent procedure with donors
Are these previously established cell lines?	• Origin & line of hESCs • Informed consent of donors
*Does your research involve the use of human embryos? **	
	• Origin of human embryos • Recruitment, inclusion & exclusion criteria • Informed consent procedure with donors
*Does your research involve the use of human fetal tissues/cells **	
	• Origin of human fetal tissues/cells • Recruitment, inclusion & exclusion criteria • Informed consent procedure with donors

What is requested?

All aforementioned topics are subject to strict authorisation.

Ethics advice related to these subjects should always be requested before the start of the research project as a

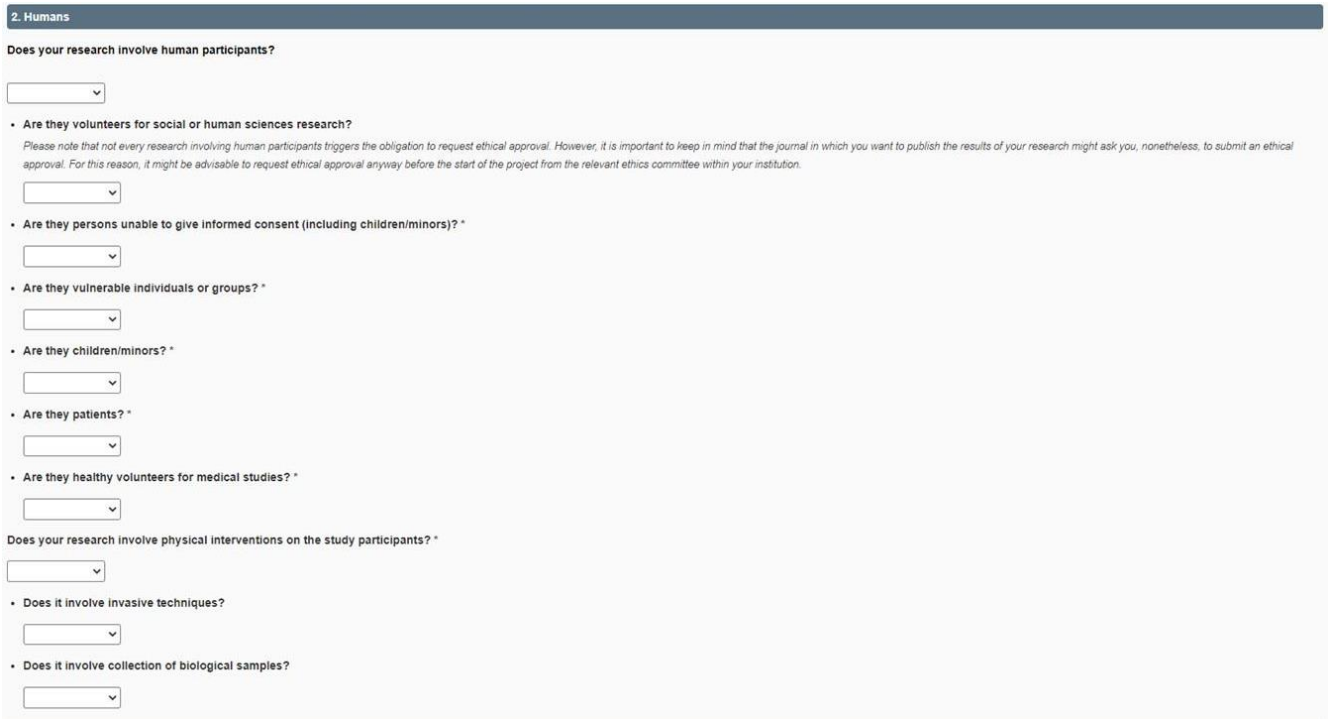
whole (as soon as your application has been approved for funding).
In addition to ethics approval by your local ethics committee, research projects using human embryos and cells derived thereof also require subsequent approval by the Federal Commission for Medical and Scientific Research on embryos in vitro (FCE). (https://consultativebodies.health.belgium.be/en/advisory-and-consultative-bodies/federal-commission-embryos).

Background documents and/or further reading (non-exhaustive)
Belgian legislation:

- Law of 11 May 2003 concerning research on embryos in vitro
- Law of 19 December 2008 regulating the procurement and use of human tissues and cells for medical application in humans or scientific research
- Royal Decree of 28 September 2009 setting standards of quality and safety in relation to the donation, harvesting, procurement, testing, processing, storage and distribution of human tissues and cells, with which human tissue banks, intermediary structures for human tissues and cells, and production establishments must comply

2. Human beings

This section refers to any research involving human study participants, regardless of its nature or topic. It may encompass: (invasive or non-invasive) collection of biological samples, medical interventions, personal data gathering, interviews, observations, tracking, secondary use of information that has been collected for other purposes, officially collected information, information extracted from social media sites, etc. The paragraphs on 'Personal data' may also apply.



Ethical checklist

Questioned research topic/methodology	Aspects to be considered
Does your research involve human participants	
Are they volunteers for social/societal or human science research?	• Recruitment, inclusion & exclusion criteria • Informed consent procedure • Measures to ensure wellbeing of subjects
Are they persons unable to give informed consent	• Recruitment, inclusion & exclusion criteria

(including children/minors[1])? * [1] a person under the age of full legal responsibility, in Belgium <18y	• Measures to ensure informed understanding of the implication(s) of participation • Procedure for obtaining approval from guardian/legal representative and the agreement of the children or other minors • Procedure to ensure subjects are not subject to any form of coercion (compulsion, threat) • Measures to ensure health & wellbeing of subjects
Are they vulnerable individuals or groups? *	• Impact & nature of vulnerability • Recruitment, inclusion & exclusion criteria • Informed consent procedure; Measures to ensure full informed understanding of the implication(s) of participation • Measures to ensure health & wellbeing of subjects
Are they children/minors *	• Recruitment, inclusion & exclusion criteria, age range • Justification for involving children/minors • Procedure for obtaining approval for guardian/parental consent and the agreement of the children/minors • Procedure to ensure subjects are not subject to any form of coercion (compulsion, threat) • Measures to safeguard health & wellbeing of subjects
Are they patients? *	• Impact of disease/condition/disability • Recruitment, inclusion & exclusion criteria • Informed consent procedure • Policy on incidental findings • Measures to safeguard wellbeing of subjects
Are they healthy volunteers for medical studies *	• Recruitment, inclusion & exclusion criteria • Informed consent procedure • Policy on incidental finding • Measures to safeguard health & wellbeing of subjects
*Does you research involve physical interventions on the study participants? **	
Does it involve invasive techniques? (collection of human cells and tissues, surgical or medical interventions, invasive studies on the brain, Transcranial magnetic stimulation, etc.)	• Risk for each individual technique & overall risk/benefit assessment
Does it involve collection of biological samples?	• What type of samples? • Procedure for collecting biological samples • Recruitment, inclusion & exclusion criteria • Informed consent procedure with donors

What is requested?

Not all research involving human participants legally triggers the obligation to request ethics approval. There might be other reasons to do so e.g. a more strict institutional policy, journal's request, etc. For this reason, it is advisable to anyway request ethics approval before the start of the project from the relevant ethics committee within your institution.

At any time, you must ensure respect for people and for human dignity and try to ensure a fair distribution of the benefits and burdens of research. You must protect the health, rights and interests of the research participants and ensure that your research methodologies do not result in discriminatory practices or unfair treatment. Moreover, you must obtain free and fully informed consent of the research participants.

Please note that when conducting surveys, interviews or focus groups where personal information is gathered and stored, you must also pay attention to privacy, personal data protection, research data management and the wellbeing and safety of participants.

Background documents and/or further reading (non-exhaustive)

Belgian legislation

- Law of 7 May 2004 concerning experiments on the human person
- Royal Decree of 30 June 2004 establishing measures for the implementation of the law of 7 May 2004 concerning experiments on the human person with regard to clinical trials on medicinal products for human use
- Royal Decree of 18 May 2006 amending the Royal Decree of 30 June 2004 establishing measures for the implementation of the law of 7 May 2004 concerning experiments on the human person with regard to clinical trials on medicinal products for human use
- Royal Decree of 04 April 2014 establishing measures for the implementation of the law of 7 May 2004 concerning experiments on the human person, with regard to the ethical committee
- Regulation (EU) no 536/2014 of the European parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing directive 2001/20/EC

Other guidelines

- WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- Oviedo Bioethics Convention

Informed consent

Research participation must at all times be entirely voluntary.

If legally or ethically required, researchers must obtain and clearly document participant's informed consent in advance.

Participants must be given an **informed consent form** and detailed **information sheets** that:

- is written in a language and in terms they can fully understand;
- describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue and what will be done to resolve these;
- explicitly state that participation is voluntary and that participants have the right to refuse participation and to withdraw their participation, and the conditions/consequences thereof (on a legal basis and/or as approved by the ethics committee) for samples and/or data obtained so far;
- state how biological samples and data will be collected and protected during the project, and, either destroyed or reused subsequently;
- state what procedures will be implemented in the event of unexpected or incidental findings (in particular, whether the participants have the right to know, or not to know, about any such findings).
- state what will happen with the data after the end of the project, if and how the data will be shared with other researchers and which measures will be taken to guarantee the confidentiality of the data, also on the long term.

It must be ensured that potential participants have fully understood the information and do not feel pressured or coerced into giving consent nor are emotional overwhelmed or overloaded with information. Participants must normally give their consent in writing (e.g. by signing the **informed consent form and information sheets**). If consent cannot be given in writing, for example because of illiteracy, phone interview or vulnerable people, non-written consent must be formally documented and independently witnessed, i.e. by a relative or trusted person that not involved in the study or associated with the research actors nor does have personal interest/benefit in the outcome of the study.

Investigations with **persons who are physically or mentally incapable of giving their consent** (for example unconscious patients), may only be conducted if being in a physical or mental state that prevents them from giving informed consent is a necessary characteristic of the group covered by the investigation. In such circumstances, the researcher should request the informed consent of the legal representative. In the absence of a legal representative and if the investigation cannot be postponed, the intervention may be started without informed consent, following conditions and procedures approved by the relevant ethics committee. Permission to keep the person involved in the investigation must be obtained as quickly as possible from the person himself or from his or her legal representative.

Research involving children/minors or other persons unable to give consent (e.g. elderly people suffering from severe cognitive impairment, persons judged as lacking mental capacity): You must obtain informed consent from the legally authorised representative and ensure that they have sufficient information to enable them to provide consent on behalf and in the best interests of the participant. Whenever possible, the assent of the participants should be obtained in addition to the consent of the parents or legal representatives. Participants who are minors are preferentially asked for consent when they reach the age of majority in the course of the research project. Dissent should be respected. If your research involves children or other individuals unable to make decisions for themselves, you must maintain an active relationship with their legal guardians and/or carers throughout the research period.

Research involving children (or other persons unable to give consent) should only be carried out if:

- studies with consenting adults would not be effective

- participants are subject to only a minimal risk and burden
- the results of the research will benefit the individual or the group they represent.

In **social science and humanities research**, there may be situations where standard procedures for obtaining written informed consent could be harmful or offensive to the participants (rather than affording them protection). In such cases, alternative consent must be obtained (e.g. orally). If deception is to be used, retrospective informed consent should be obtained and participants must be debriefed. Deception requires strong justification and appropriate assessment of the impact and the risk incurred by both researchers and participants.
Social science and humanities research often involves working with human participants and particular methodological tools (e.g. surveys, questionnaires, interviews, standardised tests, direct observation, ethnography, recordings, experiments with volunteers and sometimes physical interventions). You must therefore carefully reflect on the ethical implications of the chosen methodologies and consider ways to mitigate the harm (psychological, social, legal, economic, environmental, etc.) that might occur. Prior risk-benefit assessment is hereto crucial.

Research may expose researchers and participants to risks. Research entailing more than minimal risk typically involves:
- potentially vulnerable categories of individuals such as children/minors, patients, people subject to discrimination, people/groups unable to give consent, people of dissenting opinion, immigrant, minority communities, sex workers, etc.
- personal or sensitive topics which might induce psychological stress, anxiety or humiliation
- deception
- recruiting respondents through the internet/social media (e.g. using identifiable visual images or discussing sensitive issues).

Ensure that data are kept securely and that publication of any kind does not lead (either directly or indirectly) to a breach of agreed confidentiality. You should thereby also consider the technical aspects of collecting and storing your research data. Data collection using electronic encoding tools (digital recorders or cameras) should be given special attention.

For **medical and human research** you must follow the procedures for informed consent that are described in the Declaration of Helsinki and the Oviedo Bioethics Convention and the EU Regulation No 536/2014 on clinical trials on medicinal products for human use, transposed into Belgian legislation.

3. Human cells or tissues

This section refers to research collecting, producing or using human cells or tissues. These cells or tissues may be purchased from commercial sources or obtained/derived as part of your research project; from another research project, laboratory or research institution or from a biobank.

Ethics issues checklist

Questioned research topic/methodology	Aspects to be considered
Does your research involve human cells or tissues (other than from human embryos/foetuses)?*	
Are they obtained from commercial sources?	● Is the supplier authorised/licensed for collecting, processing and importing/exporting the human cells or tissues? ● Were the human cells or tissues donated under informed consent for intended research purpose. If not, is consent for secondary use obtained?

	• Is your lab equipped and accredited/authorised/licensed for processing human cells/tissues?
Do they originate from another laboratory/institution/biobank?	• Derived & stored in accordance with legislation of country of origin? • Were the human cells or tissues donated under informed consent for intended research purpose. If not, is consent for secondary use obtained? • Is material fully anonymized? • Destination of the material after the project period? • Is your lab equipped and accredited/authorised/licensed for processing human cells/tissues?
Were they produced or collected by you from previous research activities?	• Derived & stored in accordance to legislation? • Were the human cells or tissues donated under informed consent for intended research purpose. If not, is consent for secondary use obtained? • Destination of the material after the project period? • Is your lab equipped and accredited/authorised/licensed for processing human cells/tissues?
Are they produced or collected by you as part of this project?	• Donated under informed consent? • Source, amount and procedure for collection? • Is your lab equipped and accredited/authorised/licensed for processing human cells/tissues? • Safety classification of work place, cells/tissues appropriately screened for malignant agents & lab personal appropriately trained and protected? • Derived & stored in accordance with legislation? • Destination of the material after the project period?

What is requested?

The above topics are subject to ethics approval. If your proposal raises one of the issues listed in the ethics issues checklist, you must request ethics approval before initiation of the work concerned.

Moreover, you must keep track of the origin of the cells and tissues you use, produce or collect and must possess free and fully informed consent of the donors.

Beyond ethics aspects, the handling of cells and tissues of human origin is subject to specific rules and (safety) precautions:

- Make sure to possess/obtain the necessary accreditation/designation/authorisation/licensing for using, producing or collecting the cells or tissues (e.g., concerning donor selection/protection; accreditation/designation/authorisation/ licensing of tissue establishments and tissue and cell preparation processes; quality management of cells and tissues; procurement, processing, labelling, packaging, distribution, traceability, and imports and exports of cells and tissues from and to third countries).
- Make sure cells/tissues are safe (screened for contagious particles) and/or lab personal is appropriately protected (by proper equipment, vaccination,…).

Background documents and/or further reading (non-exhaustive)

Belgian legislation

- Law of 19 December 2008 regulating the procurement and use of human tissues and cells for medical application in humans or scientific research
- Royal Decree of 28 September 2009 setting standards of quality and safety in relation to the donation, harvesting, procurement, testing, processing, storage and distribution of human tissues and cells, with which human tissue banks, intermediary structures for human tissues and cells, and production establishments must comply
- Royal Decree on biobanks 5 February 2018

Other guidelines

- EU Tissue and Cells Directives

Secondary use
If you intend to store the material for future research in other projects, you must:
- have obtained the donor's consent for such secondary use;
- respect the legislation under which the material will be stored;
- state how long it will be stored and what you will do with it at the end of the research

Secondary use of cells or tissues from clinical practice
Human cells or tissues which have been derived from clinical practice *(e.g. waste material from surgery or other operations*) must be accompanied by the donor's informed consent for the use of their waste cells or tissues. The consent could be either for specific research or, generally, for any secondary use. If, for the purposes of your research, you intend to collect more/additional material than would normally be collected during the standard clinical procedure concerned *(e.g. a larger than normal tissue sample or a sample that includes some additional adjacent material)*, you must, on top of an ethical approval, ensure that informed consent has been given for collecting such additional material.

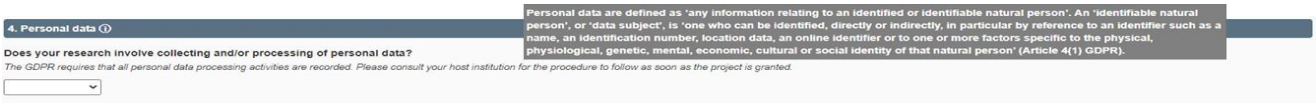
Bio-banking
'Biobanks' are repositories which obtain, treat, store and make available human body material and donor data exclusively for the purposes of scientific research. The material stored in biobanks may not be used for applications for humans. These 'libraries' thus provide researchers with access to large numbers of tissue samples, genetic material and associated data.
For ongoing scientific research, the temporary storage within the research unit of human body material in itself does not constitute an obligation to be registered as a biobank, on the condition that there is an agreement (or framework agreement) with a biobank for the use of human body material obtained for the ongoing research (within a defined time frame or for a specific purpose). However, human body material intended for future research should be stored in an established biobank or triggers the obligations to register the store as a biobank. No samples/data may be registered/placed in the biobank before all appropriate consents and ethics approvals have been obtained and procedures are in place to guarantee data privacy.

Genetic testing
For using or storing human cells or tissues for genetic testing, you must obtain the donor's informed consent for the genetic testing, and obtain approval from the relevant ethics and data protection bodies; and any licence required under national legislation.

Transfer to/from non-EU countries
If your research project involves the transfer of cells and tissues from/to non-EU countries, you must comply with the specific provisions on import/export (see also 'international collaboration'). Moreover, since human cells and tissues constitute personal data, you must also comply with the rules on data transfer to non-EU countries.

4. Personal data

This section concerns research which involves processing of personal data, regardless of the method used *(e.g. interviews, questionnaires, direct online retrieval, secondary use of personal data etc.)*. For the aspect 'personal data collection', the paragraphs on 'Human beings' may also apply.



'Personal data' means information relating to an identified or identifiable natural living person. An identifiable natural person is one who can be identified, directly or indirectly, by reference of an identifier such as a name, an identification number, location data, an online identifier or by one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person *[see EU General Data Protection Regulation (GDPR), article 4]*. Individuals are not considered 'identifiable' if identifying them requires excessive effort or resources. Consequently, completely anonymised data does not fall under the data privacy rules (as from the moment the data has been completely anonymised – the handling of anonymisation itself

still falls under the scope of the GDPR).
Personal data may come from or be used in any type of research activity *(ICT research, genetic sample collection, tissue storage, personal records (financial, criminal, education, etc.) or source (lifestyle and health information, family histories, physical characteristics, gender and ethnic background, location tracking, domicile information, etc.)*.

'Processing of personal data' means any operation (or set of operations) performed on personal data, either manually or by automatic means, even if interviewees, human volunteers, patients, etc. are *not* actively included in the research. This includes:

- collection (digital audio recording, digital video caption, etc.)
- recording
- organisation, structuring & storage (cloud, LAN or WAN servers)
- adaptation or alteration (merging sets, amplification, etc.)
- retrieval & consultation
- use
- disclosure by transmission, dissemination or otherwise making available (share, exchange, transfer)
- alignment or combination
- restriction, erasure or destruction.

The following list of personal data is considered 'sensitive' and is subject to specific processing conditions: personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs; trade-union membership; genetic data, biometric data processed solely to identify a human being; health-related data; data concerning a person's sex life or sexual orientation (Article 4(13), (14) and (15) and Article 9 and Recitals (51) to (56) GDPR).

Ethics issues checklist

Questioned research topic/methodology	Aspects to be considered
Does your research involve personal data collection and/or processing?	
• Risk/benefit analysis on used techniques (invasiveness) and consequences for rights and freedom (including privacy) of participants • Technical, organisational and preventive measures to safeguard the rights and freedom of the research participants (compliance GDPR; data protection policy for the project) • Informed consent or records concerning minors, vulnerable people or people who have not given their consent to process their personal data should include GDPR specific information (name of data controller, purpose of data processing, rights of participants etc.) • Data processing techniques Security measures to prevent unauthorised access to personal data & data transfer principles in and outside EU territory • Data minimisation principle (limit processing to data that is relevant for the project) • Anonymization/pseudonymisation methods of data (or why not?)	
Does it involve the collection and/or processing of sensitive personal data (genetic, health, sexual, lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	• Justification for the need of processing such special categories of personal data • Can research objectives not be reached by processing anonymised/pseudonymised data?
Does it involve the collection and/processing of genetic information, health or biometric data?	• Justification for the need of processing such special categories of personal data • Can research objectives not be reached by processing anonymised/pseudonymised data?
Does it involve tracking, monitoring or profiling of participants?	• Appropriateness of methods for tracking, surveillance, observation or profiling • Procedures for informing the participants about tracking & profiling and possible consequences
Does your research involve further processing of previously collected personal data ('secondary use')?	• Legitimacy of the source of the data (law of the country, permission of the owner of the data set, publicly available/social media dataset)

	● Legal ground for secondary use (f.e. informed consent) ● Preventive measures to ensure rights of the participants ● Adequate anonymization/pseudonymisation of data?

What is requested?

Research involving personal data and confidential information must comply with institutional policies and applicable EU and national law, in particular the General Data Protection Regulation (GDPR) / *Algemene Verordening Gegevensbescherming* (AVG), the national data protection laws and other applicable legislation such as e.g. in case of clinical trials).

Both data collection and data processing may possibly be subject to ethical authorisation as well.

Processing personal data in research projects is highly context-dependent and requirements for ethical advice and (centralized) procedures for registration of personal data gathering and processing diverge amongst research institutes. To ensure your research is in conformity with the institutional policy, it is essential to consult the data protection office (DPO) of your host research institution from the conceptual phase of your project. As the GDPR requires that all personal data processing activities are recorded, please consult your host institution for the procedure to follow as soon as the project is granted

Background documents and/or further reading (non-exhaustive)

Belgian legislation

- Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

Other guidelines

- VLIR : Research Data Management en de Vlaamse Universiteiten: White Paper
- Guide on good data protection practice in research

Personal data must be processed in accordance with conditions that aim to limit any possible negative impact on the persons concerned and ensure fairness, transparency and accountability of the data processing, data quality and confidentiality.

This implies at the least the following obligations:

- Data processing should be subject to appropriate safeguards. The more the data is intrusive and likely to raise ethics concerns, the higher the safeguards should be. The level of data security must be appropriate to the risks occurring for the research participants in case of unauthorized access or disclosure, accidental deletion or destruction of the data. As a researcher, you are responsible for any partners, contractors or service providers that process research data at your request or on your behalf.
- Data should wherever possible be processed in anonymised or pseudonymised form.
- Data processing is subject to free and fully informed consent of the persons concerned (unless already covered by another legal basis, *e.g. legitimate or public interest*). If consent is the legal basis, data subjects should be informed that they have the right to withdraw their consent for the processing of their personal data at any time.
- Data processing must NOT be performed in secret and research participants must be made aware that they take part in a research project and be informed of their rights and potential risks that the data processing may bring. Independent of the legal ground for the processing of personal data, the necessary information should be provided to the research participants for example in an information letter or (project specific) privacy statement.
- Data may be processed ONLY if it is adequate, relevant and limited to what is necessary for your research question(s) ('data minimisation principle').

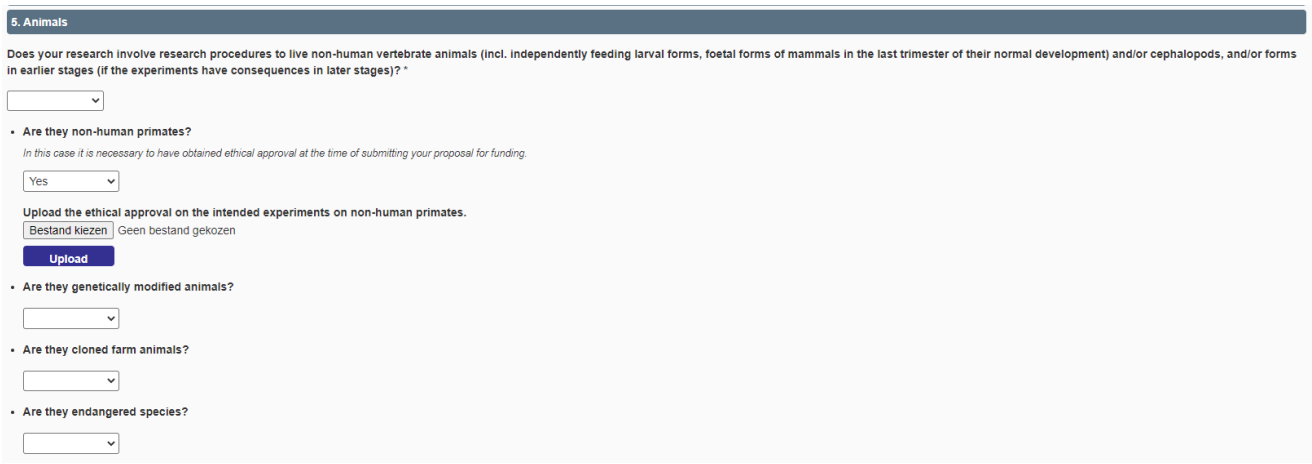
Generally, one of the recommended ways to avoid/limit data protection issues is to use anonymised or pseudonymised data.

- '**Anonymised'** means that the data has been rendered anonymous in such a way that the 'data subject' can no longer be identified (and therefore is no longer personal data and thus outside the scope of data protection law).
- '**Pseudonymised'** means that the data has been separated from its direct identifiers such that linkage to a person

is only possible with additional information that is held separately. The additional information must be kept separately and securely from the processed data to guarantee non-attribution.

5. Animals

This section refers to all research involving vertebrate animals and cephalopods (such as an octopus or squid), independently feeding larval forms, foetal forms of mammals be it in the last trimester of their normal prenatal development or also in earlier stages if the experiments have consequences in later stages of development and post-partum life.



Ethics issues checklist

Questioned research topic/methodology	Aspects to be considered
Does your research involve procedure to live non-human vertebrate animals (incl. cephalopods, independently feeding larval forms, foetal forms of mammals in the last trimester of their normal development and/or forms in earlier stages (if the experiments have consequences in later stages)?	
● Rationale for choice of species and why alternatives cannot be used ● The numbers of animals, nature of the experiments, procedures and techniques to be used ● Source of the animals[1]	
Are they non-human primates?	● Rationale for why non-human primates are the only suitable research subjects for achieving the scientific objectives ● Location, certification and available governance structures of animal housing and research facility
Are they genetically modified animals?	● Expected animal suffering (pre-and post-natal) and its severity as a consequence of resulting phenotype ● Justification for producing genetically modified animals ● Measures to minimise suffering in breeding, maintaining and using modified animals
Are they cloned farm animals?	● Expected animal suffering (pre-and post-natal) and its severity as a consequence of resulting phenotype ● Justification for cloning animals ● Measures to minimise suffering in breeding, maintaining and using modified animals

[1] LOI - WET (fgov.be): Animals may only be used in experiments if they have been bred for this purpose. Wild caught, stray animals, lost, abandoned or feral pets may not be used for animal experiments. Upon advice from the ethics committee, the public service competent for animal welfare may grant an exemption, on condition that the user files a written request with e.g. the argumentation why the intended results can only be obtained through the use of the latter type of animals. This procedure may take several months.

Are they endangered species?	• Purpose of the research • Rationale for why there is no alternative to using these animals for achieving the scientific objectives

What is requested?
You must seek alternatives to animal use when possible and implement the 'three Rs' principles (replacement, reduction and refinement). If animal experiments are necessary to obtain your scientific goals, you must ensure respect for the animals and animal welfare throughout their life cycle.

Research on live non-human vertebrate animals and cephalopods, independently feeding larval forms, foetal forms of mammals in the last trimester of their normal development and also forms in earlier stages if the experiments have consequences in later stages) is at all time subject to ethics authorisation. You must obtain appropriate ethics approval before initiation of the work concerned.

Due to the high ethical sensitivity of experimenting with non-human primates, FWO's ethical approval procedure for such project proposals differs from that for other vertebrates. Concretely, if an ethical approval is not available by the project proposal's submission deadline, the ethical approval process must have been initiated at the latest by this project application deadline. In practice, this must be proven by uploading the acknowledgment of receipt of your request for ethical advice from the Ethical Committee on Animal Testing together with your application.
The deadline for submitting the actual ethical approval to FWO is set to a fixed moment prior to the deliberations of the panels. This ethical approval must be accompanied by a signed statement detailing the possible substantive changes to the project proposal because of the iteration with the ethics committee.
The deadline for submitting ethical approval with accompanying statement is:

- for programs with a rebuttal step: the deadline of the rebuttal.
- for other projects and mandates: 1 month before the start of the panel sessions.

An exception to the above procedure is foreseen for projects that do not primarily revolve around experiments with non-human primates **and** for which, at the time of submission/evaluation, data or information is missing that is crucial to submit an ethical application (e.g. a validation experiment with non-human primates, where, within the project, preliminary experimental information has to be collected, such as e.g. dose/pharmacokinetic/pharmacodynamic values in "lower" animal species). In this case, instead of the 'ethical application' receipt from the Ethics Committee for Animal Experiments, a letter must be uploaded to the eLoket, in which an extensive and irrefutable argumentation is made as to why ethical approval is currently not possible. This letter should also include a statement signed by the applicants (i.e., minimally the promoter + co-promoter under whose supervision the primate studies take place (if different), as well as the chairperson of the appropriate ethics committee) that once the necessary info/data becomes available, an approval from the ethics committee will be requested and obtained. The argumentation for the impossibility of initiating an ethical approval before submission is an integral part of the application file. Whether or not this argumentation is accepted is within the competence of the panel and the substantive unacceptability may result in the application being declared inadmissible. If the grant is awarded, the proof of approval by the Ethics Committee must be submitted spontaneously to the FWO, at the latest 1 month before the start of the experiments in non-human primates.
If any of the aforementioned documents are missing when the project proposal is submitted and/or if the ethical approval is not received in time for the panel review, the application will be declared inadmissible.

Beyond ethical aspects, animal testing is subject to specific rules (including authorisations, restrictions on the use of certain kinds of animals, standards for handling procedures, minimum (training) requirements for personnel, recording and traceability, care, accommodation and imports and exports from and to third countries). Make sure you possess all relevant national authorisations/licensing for experimenting, producing, raising and sourcing the animal species concerned and comply with institutional policies and applicable international, EU and national law.

Background documents and/or further reading (non-exhaustive)

Belgian legislation

- Law of 14 August 1986 concerning the protection and well-being of animals
- Royal Decree of 30 November 2001 prohibiting certain animal experiments
- Royal Decree of 29 May 2013 on the protection of animal subjects
- Attachment to the Royal decree of 29 May 2013 on the protection of animal subjects
- Decree of the Flemish Government amending the Royal Decree of 29 May 2013 on the protection of laboratory animals

Other guidelines

- Joint European funding Principles for Research involving Animals

The 3R principle

An overriding principle in modern research is limiting the use of animal testing for scientific purposes. You must therefore choose alternatives to animal use whenever possible and implement the principles of Replacement, Reduction and Refinement

- **Replacement**: replacing animal use by an alternative method or testing strategy (replacing live animals by non-animal models); replacing 'higher' animals by 'lower' animals (micro-organisms, plants, eggs, invertebrates instead of warm-blooded animals, etc).
- **Reduction**: reducing the number of animals used while still ensuring scientifically sound conclusions can be drawn from the experiment.
- **Refinement**: improving the breeding, accommodation and care of animals as well as the methods used in order to minimise pain, suffering, distress or lasting harm to animals.

Specific cases:

Non-human primates (NHPs)

Since non-human primates are so close to human beings, their use in experiments raises particular ethics concerns. The royal decree of 29 May 2013 and Directive 2010/63/EU sets strict limits to their use: They may only be used for research in essential biomedical research domains for the benefit of humans, provided that no alternative/replacement methods aren't yet available. Their use is only authorized for fundamental research, for the preservation of the non-human primate species involved, or for research activities, including xenotransplantation, related to life-threatening human conditions or to cases that have a material impact on people's daily functioning. Only offspring of non-human primates which have been bred in captivity or which are sourced from self-sustaining colonies may be used.

Endangered species

Endangered species cannot be used, except for very important research purposes and where there is no alternative non-endangered species that will meet the scientific objective. You should follow agreed international practices (CITES).

Exemptions for particular animal experiments:

An additional exemption is required for the following types of animal experiments (see Royal Decree 29/5/2013): Field trials (art.17); Serious, lengthy tests (art.18, §5); use of another euthanasia method than those stated in Appendix 7 of Royal Decree (art. 33).

6. Access and Benefit Sharing and the Nagoya Protocol

This section refers to all research involving genetic resources and/or traditional knowledge associated with genetic resources, as covered by the EU Regulation related to the Nagoya Protocol.

In the 'Access and Benefit Sharing legislation', more specifically in the EU-legislation related to the Nagoya Protocol, '*genetic resources*' are defined as 'any material of plant, animal, microbial or other origin containing functional units of heredity and that is of actual or potential value'. '*Traditional knowledge associated with genetic resources*' means 'knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources'.

Ethics issues checklist

Questioned research topic/methodology	Aspects to be considered
Does your research involve genetic resources or traditional knowledge associated with genetic resources, that are captured by the EU Regulation related to the Nagoya Protocol?	● provider country's conditions of access ● Benefit sharing measures ● Due diligence on all relevant permissions, proper record keeping and the submission of due diligence declarations. ● Responsiveness to local (research) need ● Measures to ensure local capacity building

What is requested?

Researchers have a legal obligation to comply all legislation related to the Nagoya Protocol. The Protocol applies only to genetic resources accessed 1) from a country that is party to the Nagoya Protocol and that has Access and Benefit-sharing (ABS) legislation and 2) for the purpose of 'utilization of genetic resources' after 12th October 2014. The protocol applies both to those who obtain genetic resources directly from the country of origin and those who obtain them indirectly from third parties, but does not apply to human genetic resources, genetic resources already governed by specialised international instruments (e.g. the International Treaty on Plant Genetic Resources for Food and Agriculture) nor genetic resources as traded commodities.
Consult http://nagoya.vlir.be/ for the checklist to determine whether the Nagoya Protocol applies to the material and get more information on the procedure to follow as soon as the project is granted, if applicable.

Background documents and/or further reading (non-exhaustive)

Belgian legislation
Ontwerp van decreet betreffende de toegang tot genetische rijkdommen en de eerlijke en billijke verdeling van voordelen voortvloeiende uit hun gebruik

Other guidelines

- http://nagoya.vlir.be/
- Nagoya Protocol on Access and Benefit Sharing
- Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union
- Commission Implementing Regulation (EU) 2015/1866
- Guidance document 2021/C 13/01 on the scope of application and core obligations of the 2014 regulation
- An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing
- ABS clearing house

Resources from a non-EU country
Any use of 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, fossils), traditional knowledge or combinations thereof] must show respect for biological diversity, cultural traditions and share benefits (i.e. benefit to local participants and their communities, involvement of local researchers as equal partners and responding to local research needs). This is particularly important for low income and lower-middle income countries (see Convention on Biological

Diversity and Declaration of Helsinki and follow the Global code of conduct for research in resource-poor settings).

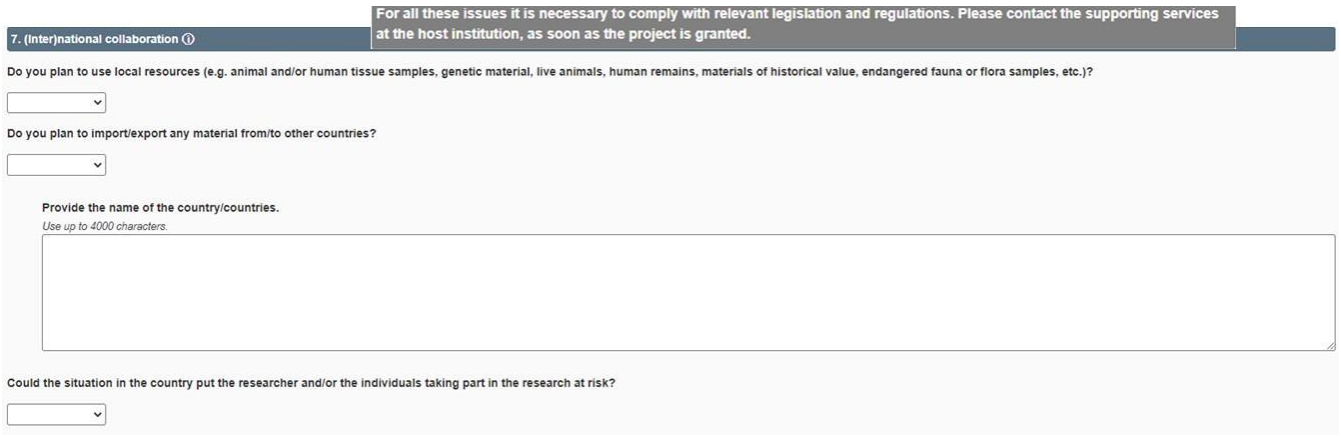
Access to and import/export of genetic resources
For access to genetic resources of animal, vegetable, microbial or other origin, you must also comply with the Nagoya Protocol on Access and Benefit Sharing and EU Regulation (EU) No 511/2014 which implements this Protocol. The Nagoya Protocol / Access and Benefit Sharing (ABS) protocol regulates access to genetic resources (any material of plant, animal, microbial or other origin containing functional units of heredity and that is of actual or potential value) and/or associated knowledge/data and the fair and balanced distribution of benefits arising from their use.

Pivotal aspects of the protocol are:
• from the user's side: comply with the ABS regulations applicable in the supplying countries
• from the supplying country's side: comply with the applicable national legislation (and associated governmental control system) on access to genetic resources and/or the traditional knowledge of indigenous and local communities associated with it. Right to use may legally be made conditional on clear agreements based on prior informed consent of the supplying country and mutually agreed terms on the conditions for the export, the terms of utilisation and the distribution of profits arising from the use of resources with the supplying country.

If tangible materials are transferred across borders, it may be mandatory under the law of the supplying and/or receiving country to obtain an authorisation for export, respectively import.

7. International collaboration

This section concerns research involving non-EU countries.



Research in countries that do not fall under Belgian and European laws and standards (including research activities, participants, imported/exported resources) can raise specific ethical issues (particularly in lower and lower-middle income countries), such as:

- exploitation of research participants
- risks to participants and researchers
- exploitation of local resources
- research that is prohibited in the EU (ethics dumping)

Ethics issues checklist

Questioned research topic/methodology	Aspects to be considered
Do you plan to use 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.)?	● Justification and risk-benefit analysis + Human resources: see paragraph on human beings and personal data + Vertebrate resources: see paragraph on animals + other animals, plants, micro-organisms, genetic resources & traditional knowledge: see paragraph on access permit, benefit Sharing and the Nagoya

	Protocol
Do you plan to import/export any material from/to other countries?	● Type of material [non-living, living, human-derived materials (including human remains), personal data, genetic resources, traditional knowledge, artefacts of historical value] ● Country- & material-related risk-benefit analysis ● Compliance to import/export legislation
Could the situation in the country put the individuals taking part in the research (i.e. both researchers and participants) at risk?	● Justification and risk-benefit analysis ● Health and safety measures (training staff, insurance, preventive measures to ensure rights of the participants …)

What is requested?

In order to prevent ethics dumping, ethically sensitive activities must comply both with the legal obligations in the concerned non-EU country, and with those in force in Europe/Flanders. Therefore, a double ethics verification procedure has been implemented for research in non-EU countries. For EU countries, ethical approval in the country where the research is conducted suffices, given that across Europe, EU ethics regulations follow national legislation.

1. Ethical approval must be obtained in the non-EU country where the project is to be executed and for clinical and animal testing necessary governance structures have to be in place locally. Also for other types of research involving human participants (e.g. behavioural or sociological research) require institutional, regional or national consent (whether or not by an ethics committee) and / or community-level consent. It is the researcher's responsibility to gather the necessary information on local structures and conditions and to understand whether or not the research project requires ethical approval in the non-EU country. The ethical approval or the reasoning for not obtaining them (e.g. the research described does not require local ethical approval) must be documented.
2. Simultaneously, the responsible ethics committee of a Flemish (or European) research institution must assess whether the proposed research complies with fundamental ethical principles (such as for example for human experiments contained in the 'Declaration of Helsinki ') and the spirit and principles of the national / European regulations in force.

If one of the parties involved believes that there is a risk of opportunistic shifting of ethically inadmissible, problematic or controversial practices and / or if it cannot sufficiently guaranteed that the research can be carried out in an acceptable manner, the proposed research cannot take place using FWO funds. It is advisable to conduct research within the EU if there is no specific need to carry it out outside the EU for a particular reason.

The responsible researcher (coordinator) of the FWO project is requested to provide the supporting documents from the non-EU country to its host institution's responsible service, where they are kept at the disposal of the FWO.

Background documents and/or further reading (non-exhaustive)

Other guidelines

- Human resources
  - Declaration of Helsinki
- Flora & fauna
  - Convention on Biological Diversity
- Developing countries and lower income settings
  - Global code of conduct for research in resource-poor settings

Ethics dumping

The continuing globalization of research activities increases the risk that ethically sensitive research is conducted abroad in a manner that would not be tolerated from an ethical point of view in Flanders (= Ethics dumping). Although there

will always be variations between ethical standards, regulations, legislation and human practices, researchers should make every effort to ensure that research that they conduct themselves abroad, or that is carried out by others under their supervision / responsibility, is performed in accordance with the applicable laws of the foreign partner country as well as according to the ethical principles applied in Flanders and the host institution. International collaborations however have to be conducted in an equivalent, respectful and mutually beneficial partnership with local scientific and societal stakeholders (http://www.globalcodeofconduct.org/). It is in this respect thus also important to consider the unethical character of the unilateral imposition of norms and values from a dominant ethical and / or legal perspective as this can create an additional sensitivity, for example in cooperation with developing countries.

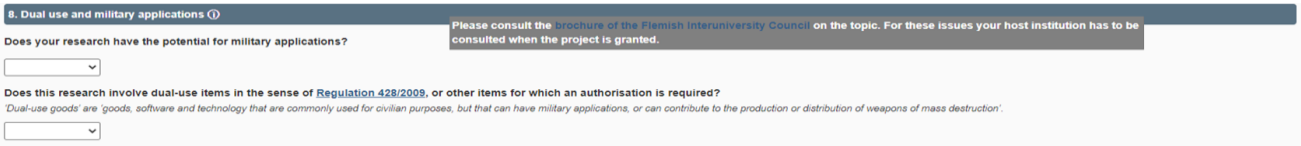
International cooperation outside Europe in the context of FWO supported research projects and / or fellowships is only permitted if there are sufficient mechanisms in place to guarantee respect for the rights of the participants at all times.

FWO-supported experiments with/on humans, irrespective of whether these are interventional or observational studies, must therefore always comply with the legal, ethical standards in the country where they are carried out, but also with minimum standards regarding, among other things, informed consent, care and experimental procedures as described for Belgium in, *inter alia*, the Law of 7 May 2004 (Experiments on the Human Person Act), the Royal Decrees of 2004, 2006 and 2014, and the EU Regulations 536/2014 (clinical trials) and 2016/679 (GDPR).
Animal testing carried out outside the EU in the context of FWO-supported research must equally respect legal, ethical and normal practices in the country concerned, as well as minimum standards for animal welfare, animal housing, care and experimental procedures. This therefore implies compliance with the principles of the 1986 Law, the Royal Decrees of 2001 and 2013 and the rationale of Directive 2010/63/EU of the European Parliament and Council.
For these reasons, it is appropriate to conduct research that does not necessarily need to be conducted outside the EU for a specific reason, within the EU. Institutions and subcontractors where or with which this research is carried out must be transparent and verifiable in the area of compliance with ethical and legal standards.

Research activities that require ethical approval in Belgium may under no circumstances be initiated before permission has been obtained in both the non-EU country and within the EU.

8. Dual & military applications

This section concerns research involving goods, software, knowledge, methodology and technologies that are normally used for civilian purposes but may have partial or full military applications, and/or may contribute to the proliferation of chemical, biological or nuclear weapons of mass destruction.



Research proposals that in full and unambiguously aim for military applications with an offensive character are not eligible for FWO funding.
Projects on technologies and goods that could be used for both civilian and military purposes, or involving military partners, are only eligible for funding if the civilian applications and benefits are made sufficiently clear.
See for more information: VLIR brochure dual use.

8.1 Ethics issues checklist

Questioned research topic/methodology	Aspects to be considered
Does your research have the potential for military applications?	• Justification and risk-benefit analysis (during and beyond the lifetime of the project) • Focus civil vs. military applications • Potential applicability in conventional, chemical or biological war-fare and security • Potential applicability in interrogation techniques and/or torture

	• Collaboration with (people from) countries that are under (weapon)embargo/sanctioned or firms producing weapons • Likelihood that national authorities will grant the required authorisation(s)/license(s). • Security risks (during and beyond the lifetime of the project) and training for researchers
Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?	• Item list screening: 10 broad categories: ○ Nuclear materials, facilities and equipment ○ Special materials and related equipment ○ Materials processing ○ Electronics ○ Computers ○ Telecommunications and "information security" ○ Sensors and lasers ○ Navigation and avionics ○ Marine ○ Aerospace and propulsion Five groups: ○ Systems, equipment and components ○ Test, inspection and production equipment ○ Materials ○ Software ○ Technology (strategic knowledge) • Trajectory screening: is the country of destination or the country of end use subject to an embargo or sanction? • End use and end-user screening: who will use your research results, what do they do and what will the results be used for?

What is requested?

Research with dual-use or possible military applications is subject to authorization and/or ethics approval. If your proposal involves dual-use items in the sense of EU council regulation No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items, an export authorization might be necessary. Export of dual-use items, software and knowledge to non-EU countries is subject to regulations to counter their undesirable and uncontrolled proliferation. Export may include the publication of the research results or sharing the results in any other way.
In addition, when working on dual-use or possible military applications, the project might need ethics approval within the host research institution. For these issues the policy of your host institution has to be followed.

Background documents and/or further reading (non-exhaustive)

Belgian legislation/guidelines

- 'Controle Strategische Goederen' Belgium
- 'IWT richtlijn rond overheidssteun aan onderzoeksprojecten met een mogelijke militaire finaliteit (dd. 27/5/1994)'
- VLIR brochure dual use

Other guidelines

- Guidance note — Research involving dual-use items
- Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items
- Biological and Toxin Weapons Convention
- UN Security Council Resolution 1540
- Treaty on the Non-Proliferation of Nuclear Weapons (NPT)
- Chemical Weapons Convention
- Council Common Position 2003/805/CFSP on the universalisation and reinforcement of multilateral agreements in the field of non-proliferation of weapons of mass destruction and means of delivery

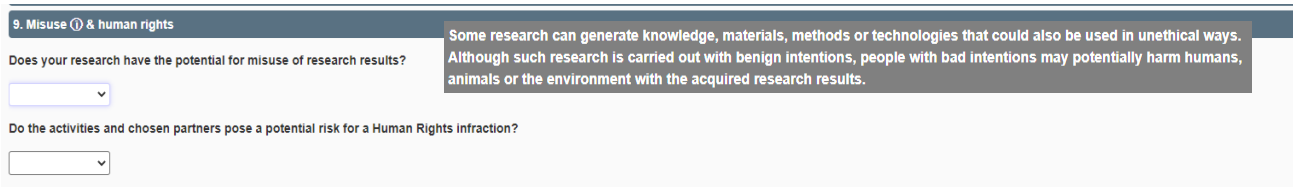
- EU Regulation No 2913/92 establishing the Community Customs Code
- dual-use trade controls
- Guidance note — Research with an exclusive focus on civil applications
- https://www.sanctionsmap.eu/

Cross-border transfers
For cross-border transfers of dual-use materials, technologies and information, you must comply with the EU Export Control Regulation No 428/2009. The researcher must contact, via the centrally designated services of his knowledge institution, the 'Strategic Goods Control service' of the Flemish Government (or for institutions based in the Brussels Capital Region, the Brussels Export Control Service) for the application for a license for the export of dual use items to countries outside the EU and, for highly sensitive items, even to countries within the EU.

Research that may affect ethics standards
If international non-proliferation laws or international humanitarian laws may have a bearing on your research (e.g. in the case of pathogen-related research, development of autonomous robotics, drones and certain laser technologies), you must comply with the relevant international law (in particular, the Biological and Toxin Weapons Convention).

9. Misuse & human rights

This section concerns research, although carried out with benign intentions, that involves or generates materials, methods, technologies or knowledge that could be misused for unethical purposes and/or has the potential to harm humans, human rights, animals or the environment.
Although almost anything could ultimately be used for malevolent purposes, this category is aimed at research which provides individuals with malevolent intentions with information or technologies that would have direct and substantial impact on the security or human rights of individuals, groups or states.



Ethics issues checklist

Questioned research topic/methodology	Aspects to be considered
Does your research have the potential for misuse (malevolent/criminal/terrorist abuse) of the research results?	● Risk assessment ○ Could the materials/methods/technologies and knowledge concerned harm people, animals or the environment if modified or enhanced?? ○ What if the research results end up in the wrong hands? Could they serve any purposes other than the intended ones? If so, would that be unethical? ● Legal requirements ● Measures to prevent misuse (adjusted safety and security measures during and beyond the lifetime of the project)
Is it likely that activities or partners violate human rights?	● Risk assessment to assess whether ○ The research involves developing surveillance technologies, data-gathering and data-merging technologies could curtail human rights and civil liberties. ○ The research involving minority or vulnerable groups or developing social, behavioural or genetic profiling technologies could be misused to stigmatise, discriminate against, harass or intimidate people.

	○ state actors, government laws and policies and/or social or cultural norms in the partner's country pose a risk for human right infraction, and whether the partner somehow contributes to this. ○ Partner organisations seriously or systematically violate human rights (such as discriminating on the basis of gender, political opinion or religion, not respecting the right to free speech, , …), even though the activities themselves do not risk violating human rights

What is requested?

If there's a potential for misuse of the research results, you must obtain an ethical approval from the relevant ethics committee within you institution.

In order to prevent benefiting from human rights violations, activities should be preceded by a human rights impact assessment. If it looks like the activity, partner, sector or region is tied to serious or systematic human rights violations, you must submit the intended activities to the relevant ethics committee within your institution.

Misuse

The research most vulnerable to misuse is research that:

- Provides knowledge, materials and technologies that could be channelled into crime or terrorism
- Could result in chemical, biological, radiological or nuclear weapons and the means for their delivery
- Involves developing surveillance technologies that could curtail human rights and civil liberties
- Involves minority or vulnerable groups or develops social, behavioural or genetic profiling technologies that could be misused to stigmatise, discriminate against, harass or intimidate people.

When designing a proposal, consider not only the immediate aims and intended applications of the activities you plan, but also whether your research could serve unethical purposes. You should also examine whether there are any risks that will outlast the project itself.

There are various ways to mitigate risk. Depending on the activity planned and the potential misuse, applicants may choose to:

- Take additional security measures, e.g. physical security measures, classification of certain deliverables, compulsory security clearance for those involved in the project
- Take additional safety measures, e.g. compulsory safety training for staff
- Adjust the research design, e.g. use dummy data
- Limit dissemination, e.g. by publishing only part of the research results, regulating export, etc.

Research with a potential impact on human rights and freedom

Concerns in this field relate primarily to research on surveillance technologies, new data-gathering and data-merging technologies (e.g. in the context of big data). However, social or genetic research that could lead to discrimination or stigmatisation is also affected. Risk mitigation measures may include:

- a human rights impact assessment
- involving human rights experts in your research
- training personnel and/or technological safeguards
- caution when publishing or otherwise disseminating results (e.g. through privacy by design)
- adapting the research design (e.g. using dummy data).

In many cases, researchers outside the security domain are not familiar with security safeguards. In such situations, researchers should consult experts familiar with security ethics and/or human rights. If security or human rights abuse concerns exist, you should arrange for training on this issue and appointment an ethics adviser/ethics advisory board.

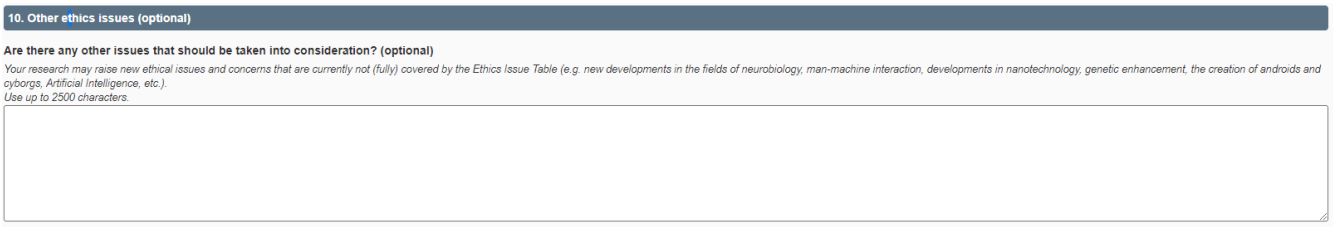
Background documents and/or further reading (non-exhaustive)

- EC Guidance note — Potential misuse of research
- Responsible life sciences research for global health security: A guidance document

- Human right impact assessment (VLIR)

10. Other ethics issues (optional)

Since FWO intends to support ground-breaking and innovative research, it may be that your research raises **new ethical issues and concerns** that are currently not (fully) covered by the Ethics checklist. Amongst other may be new developments in the fields of neurobiology, artificial intelligence, man-machine interaction, developments in nanotechnology, genetic enhancement, the creation of androids and cyborgs, design, production, use or governance of artificial intelligence, robots or "autonomous" technology (e.g. self-driving cars and drones, robots in deep sea and space exploration, robotic weapon systems, software agents, deep learning, …).



If you are aware of any such other ethically relevant issues that apply to your project, describe them and explain how you intend to address them. This allows you to alert the expert panel and get appropriate input for addressing them. It could also avoid problems you would encounter if such issues were found out only later (e.g. in the context of publication requirements or audits). Use the 'ethics by design' methodology.

What is requested?

Background documents and/or further reading (non-exhaustive)
Guidelines
General information on ethics

- Ethics for Researchers
- European Textbook on Ethics in Research (2010)
- Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects

Food-related research

- FP7 guidance: Guidance Note — Ethics and Food-Related Research

Research related to artificial intelligence (AI)

- Ethics guidelines hhttps://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-aifor trustworthy AI

Research related to vulnerable people

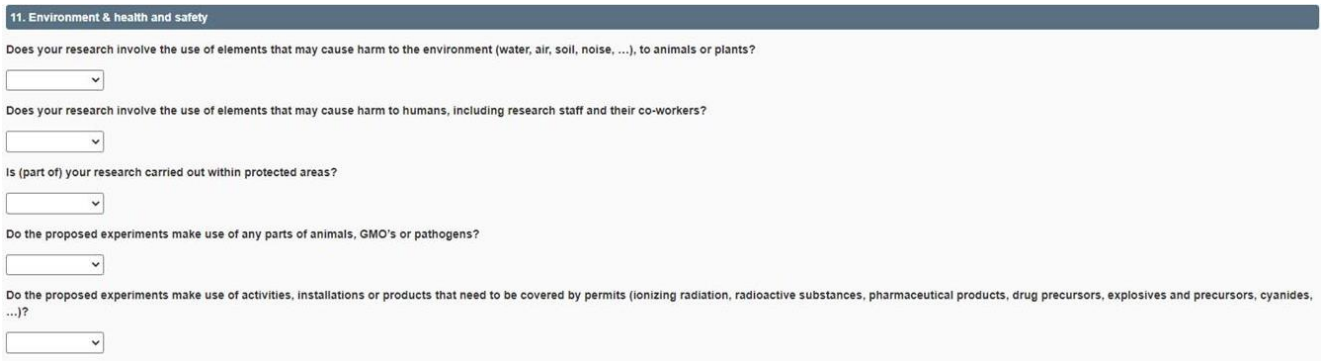
- Guidance note — Research on refugees, asylum seekers & migrants

Research related to Social Sciences and Humanities

- Ethics in Social Science and Humanities

11. Environment, health & safety

This section concerns research that may adversely affect the environment and/or the physical and psychological health & safety of the researchers, research subjects and third parties involved. This may be related to the topic, experimental design of the research and/or research setting and/or undesirable side-effects of the technologies used.



Ethics issues checklist

Questioned research topic/methodology	Aspects to be considered
Does your research involve the use of elements that may cause harm to the environment (water, air, soil, noise, …), to animals or plants?	• Justification and risk-benefit analysis • Safety classification of work place • Environmental authorisations/licensing for using, producing storing and disposal of substances • Precautionary principles (now and in the future) and health & safety measures • Training of staff
Does your research involve the use of elements that may cause harm to humans, including research staff and their co-workers?	• Justification and risk-benefit analysis for physical and/or psychological harm • Safety classification of work place • Health and safety authorisations/licensing for using, producing storing and disposal of substances • Precautionary principles (now and in the future) and health & safety measures • Training of staff
Is (part of) your research carried out within protected areas?	• Justification and risk-benefit analysis • Precautionary principles (now and in the future) and health & safety measures
Do the proposed experiments make use of any parts of animals, GMO's or pathogens?	• Precautionary principles (now and in the future) and health & safety measures • Safety classification of work place & containment measures • Environmental authorisations/licensing for using, producing storing and disposal of tissues, GMO's or pathogens • Training of staff
Do the proposed experiments make use of activities, installations or products that need to be covered by permits (ionizing radiation, radioactive substances, pharmaceutical products, drug precursors, explosives and precursors, cyanides, …)?	• Justification and risk-benefit analysis for physical harm • Safety classification of work place • Authorisations/licensing for using, producing storing and disposal of substances • Precautionary principles (now and in the future) and health & safety measures • Training of staff

What is requested?

The health and physical and psychological safety of all human participants in research – such as subjects, investigators or uninvolved third parties, must be a priority at all times. At all time, be attentive for the impact gender, religion, sexual orientation, race, ethnicity and disability of the researcher(s) may have on their safety, in particular in certain nations. You must also assess potential risks to the environment and avoid or minimise such risks. Staff should receive adequate training.

Research must particularly comply with the precautionary principle and legislation on nature conservation and pollution control. The precautionary principle requires that where there is plausible scientific evidence for serious risks, you must assess that a new technology will not harm the future users and/or environment.

The handling of environmentally harmful substances while researching is subject to specific health and safety authorisations (e.g., on licensing of establishments; procurement, processing, labelling, packaging, distribution, traceability, public-health control and imports and exports of those substances from and to third countries;). This is particularly true for activities, installations or products that need to be covered by federal permits (ionizing radiation, radioactive substances, pharmaceutical products, drug precursors, explosives and precursors, cyanides, GMO, pathogens…). Make sure to also possess the necessary environmental authorisations/licensing for using, producing storing and disposal of substances and implement the necessary preventive and curative checks and procedures and training at the workplace.

Background documents and/or further reading (non-exhaustive)

Belgian legislation

http://www.reachinbelgium.be
http://www.werk.belgie.be/home.aspx
https://www.lne.be/milieuvergunningendecreet-vlarem-i-ii-en-iii

Other guidelines

General environment

- EU Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p.7)
- EU Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 103, 25.4.1979, p.1)
- Cartagena Protocol on Biosafety
- EU Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)
- EU Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)

GMOs

- EU Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on trans-boundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1)
- EU Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75)

Public health & consumer protection

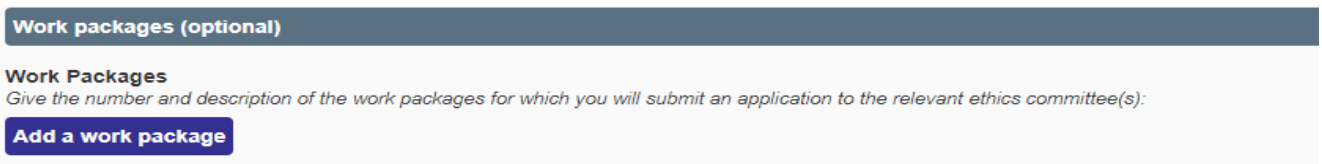
- Consumer safety

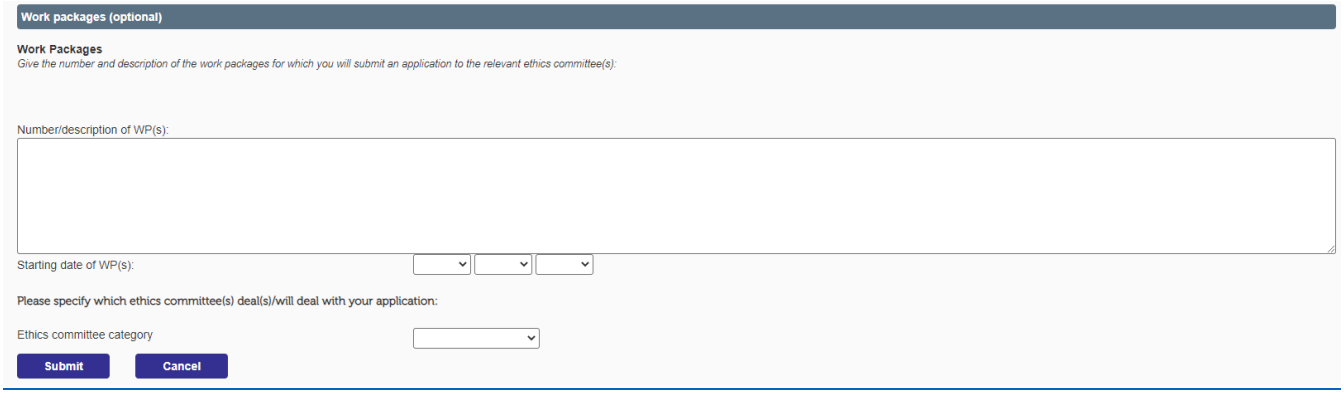
Health & safety at work

- EU Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of the workers to risks arising from physical agents (OJ L 114, 27.4.2006, p.38)
- A Code of Practice for the Safety of Social Researchers
- Bio-risk management: Laboratory biosecurity guidance

12. Details on ethically sensitive issues per work package

For a better understanding by the reviewers and/or panellists, please provide further details on the work packages for which you will seek ethics approval. You can add additional work packages as needed.





13. Declaration

Every FWO applicant must tick the box on the ethics statement that applies to the relevant submission.

- ○ **I confirm that none of the issues above apply to my proposal.**
- ○ **I hereby confirm having taken note that an ethical approval is needed for issues indicated with an asterisk (*) and/or that I will adhere to all relevant legislation and institutional policies pertaining to issues with or without asterisk (*) that apply to my proposal. If an ethical approval is required, I will ensure to obtain this approval from the competent ethics committee of my host institution, at the latest before starting with the ethical sensitive activities.**

Ethical guidance

Ethics advisors/advisory boards
A suitably experienced ethics adviser may help you to deal with ethical concerns and putting into place procedures to handle these appropriately. If your research involves numerous significant or complex ethical issues, you may consider appointing an ethics advisor or ethics advisory board with several experts with varied expertise. FWO leaves it up to the discretion of the researcher to determine whether the appointment of ethics advisers or advisory board is of added value for her/his project.

An ethics adviser or ethics advisory board should maintain an full overview of (the progress of) your research activities throughout the course of your project and help you to think ahead about possible problems that might arise and how they can be addressed. Their experience will help you check for compliance with ethical standards within the relevant research fields. They will also be responsible for reporting to you, the host research institution, funding agency and others involved on ethics concerns as they arise and the continuing integrity of your studies.

If you appoint an ethics adviser/advisory board, it is important that they are independent to the project, free from any conflict of interest and preferentially external to the host research institution.

This guideline is designed to provide applicants some background information on and help them with the ethical self-assessment that is compulsory for application to any form of FWO funding. The first source of information and your primary point of contact for information about the ethics committees and the local procedure for requesting ethical advice lays however within your host research institution.

KU Leuven
- https://www.kuleuven.be/english/research/ethics

UAntwerpen
- https://pintra.uantwerpen.be/webapps/ua-pintrasite-BBLEARN/module/index.jsp?course_id=_48_1&tid=_11990_1&lid=_12034_1&l=en_us

UGent
- https://www.ugent.be/intranet/nl/op-het-werk/onderzoek-onderwijs/onderzoek/beleid/kwaliteit/ethiek.htm

UHasselt:
- https://www.uhasselt.be/Contactpunt-Ethiek-Integriteit

VUB:
- https://www.vub.be/onderzoek/legal-ethics-office#home

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Analogous to the ethical self-assessment procedure of FWO, this guideline is grounded in the document '*Horizon 2020 Programme – Guidance: how to complete your ethics self-assessment Version 6.1 dd. 4/2/2019*' of the European Commission's Directorate-General for Research & Innovation. The original document can be found here:
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

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