# Introduction

Research at Ghent University should be conducted according to ethical standards. Some are imposed by law, others are generally accepted in (international) scientific practice.

Researchers at Ghent University must reflect on the ethical aspects in their research project and indicate these by means of the questionnaire. Sometimes there is a legal obligation to submit the dossier to an ethics committee, which is also indicated in the questionnaire. However, researchers may also contact the ethics committees for an ethical approval if there is no legal obligation, e.g., when a journal requests an ethical approval. Check our website in [Dutch](https://www.ugent.be/intranet/nl/op-het-werk/onderzoek-onderwijs/onderzoek/context/ethiek/ethisch-advies.htm) or [English](https://www.ugent.be/intranet/en/research/ethics/ethics-approval.htm).

Via this link you can find more information on how to complete the ethics questionnaire : [Ethics: How do I complete the ethics questionnaire for a BOF or IOF application? | (re)search tips (ugent.be)](https://onderzoektips.ugent.be/en/tips/00001933/).

# Ethics questioNnaire

## Human embryos/foetuses

|  |  |
| --- | --- |
|  | YES? |
| 1. Does your research involve human Embryonic Stem Cells (hESCs) 2. Will the hESCs be directly derived from embryos within this project? 3. Are the hESCs previously established cell lines? |  |
| 1. Does your research involve the use of human embryos? |  |
| 1. Does your research involve the use of human foetal tissues / cells? |  |

If you checked any of the boxes, you must submit your proposal to the Committee for Medical Ethics, as soon as your application has been approved for funding. The project can only start when the committee has formally given an ethical approval of the project.

Additionally, if you checked the box for question 2, research projects using human embryos *in vitro* require subsequent approval by the Federal Commission for Medical and Scientific Research on embryos in vitro (FCE).

## Humans

|  |  |
| --- | --- |
|  | YES? |
| 1. Does your research involve human participants? 2. Are they volunteers for social or human sciences research? 3. Are they persons unable to give informed consent (including children/minors)? 4. Are they vulnerable individuals or groups? 5. Are they children/minors? 6. Are they patients? 7. Are they healthy volunteers for medical studies? |  |
| 2. Does your research involve physical interventions on the study participants?  a. Does it involve invasive techniques?  b. Does it involve collection of biological samples? |  |

If you checked box 1.a, 1.b, 1.c or 1.d, please note that not every research involving human participants triggers the obligation to request an ethical approval. However, the journal in which you want to publish the results of your research might ask you to submit an ethical approval. For this reason, it might be advisable to request ethical approval anyway before the start of the project from the relevant ethics committee.

If you checked box 1.e, 1.f or 2, you must submit your proposal to the Committee for Medical Ethics, as soon as your application has been approved for funding. The project can only start when the committee has formally given an ethical approval of the project.

## Human cells/tissues

|  |  |
| --- | --- |
|  | YES? |
| 1. Does your research involve human cells or tissues (other than from human embryos/foetuses)? 2. Are the human cells or tissues obtained from commercial sources? 3. Do they originate from another laboratory/institution/biobank? 4. Were they produced or collected by you during previous research activities? 5. Are they produced or collected by you as part of this project? |  |

If you checked any of the boxes, you must submit your proposal to the Committee for Medical Ethics, as soon as your application has been approved for funding. The project can only start when the committee has formally given an ethical approval of the project.

## Personal data

|  |  |
| --- | --- |
|  | YES? |
| 1. Does your research involve collecting and/or processing of personal data? |  |

If you checked the box, the GDPR requires that all personal data processing activities are registered in the processing register of each institution where the processing takes place as soon as the process is granted. At UGent, the processing of personal data should be included in ‘my DMP’ (via DMPonline.be). The processing of personal data has to be registered separately. Check our [website](https://onderzoektips.ugent.be/en/tips/00001795/) for more information.

## Animals

|  |  |
| --- | --- |
|  | YES? |
| 1. Does your research involve research procedures to live non-human vertebrate animals (incl. independently feeding larval forms, foetal forms of mammals in the last trimester of their normal development) and/or cephalopods, and/or forms in earlier stages (if the experiments have consequences in later stages)? 2. Are they non-human primates? 3. Are they genetically modified animals? 4. Are they cloned farm animals? 5. Are they endangered species? |  |

In case you checked box 1.a, you must have obtained an ethics approval at the time of submitting your proposal for funding. In case you checked box 1.b, 1.c or 1.d, you must submit your proposal to the ethics committee responsible for your faculty as soon as your application has been approved for funding. The project can only start after formal approval of the project by the ethics committee. Please submit your proposal to one of the following ethics committees:

* + - * Ethics Committee for Animal Research of the Faculty of Sciences and VIB-UGent;
      * Ethics Committee for Animal Research of the Faculty of Veterinary Medicine, also for the Faculty of Bioscience Engineering;
      * Ethics Committee for Animal Research of the Faculty of Medicine and Health Services, also for the Faculty of Pharmaceutical Sciences and University Hospital Ghent.

Check our website in [Dutch](https://www.ugent.be/nl/onderzoek/maatschappij/dierproeven/overzicht.htm) or [English](https://www.ugent.be/en/research/research-strategy/animal-research.htm) for more information.

## Access and Benefit Sharing and the Nagoya Protocol

|  |  |
| --- | --- |
|  | YES? |
| 1. Does your research involve genetic resources and/or traditional knowledge associated with genetic resources, that are captured by the EU Regulation related to the Nagoya Protocol?   a. Name of the country/ies of origin: ……………………………………………………….. |  |

You usually must obtain a ‘Prior Informed Consent' (PIC) from the Competent National Authority (CNA) in the country of origin (provider country) prior to the access and utilization of the genetic resources or traditional knowledge. The conditions for utilization, and benefit sharing, must be negotiated and registered in 'Mutually Agreed Terms' (MAT). Check our [website](https://www.ugent.be/intranet/en/research/ethics/nagoya) for more information.

## International collaboration

|  |  |
| --- | --- |
|  | YES? |
| 1. 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.)?    1. Name of country/ies: …………………………………………………………………... |  |
| 1. Do you plan to import/export any material from/to other countries?   a. Name of country/ies: ……………………………………………………………………. |  |
| 1. Could the situation in the country put the researcher and/or the individuals taking part in the research at risk |  |

For more information, please consult [Ethics: How do I complete the ethics questionnaire for a BOF or IOF application? | (re)search tips (ugent.be)](https://onderzoektips.ugent.be/en/tips/00001933/).

## Dual-use and military applications

|  |  |
| --- | --- |
|  | YES? |
| * + 1. Does your research have the potential for military applications? |  |
| * + 1. Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an export license is required? |  |

If you checked any of the boxes, be aware that research proposals with potential military applications or involving dual-use items must comply with Ghent University’s dual-use research policy and must be reported to Ghent University’s Dual-Use Contact Point. You might need an export license if you wish to export dual-use items. Check our website in [Dutch](https://www.ugent.be/intranet/nl/op-het-werk/onderzoek-onderwijs/onderzoek/context/ethiek/dualuse) or [English](https://www.ugent.be/intranet/en/research/ethics/dual-use) for more information.

Not every dual-use research triggers the obligation to request an ethical approval. However, the journal in which you want to publish the results of your research might ask you to submit an ethical approval. For this reason, it might be advisable to request an ethical approval from the Committee on Human Rights Policy and Dual-Use Research anyway before the start of the project.

## Misuse & human rights

|  |  |
| --- | --- |
|  | YES? |
| 1. Does your research have the potential for misuse of the research results? |  |
| 1. Could the research contribute to human rights violations, or is a project partner involved in human rights violations? |  |

If you checked box 1, know that not all potential for misuse of the research results triggers the obligation to request an ethical approval. However, the journal in which you want to publish the results of your research might ask you to submit an ethical approval. For this reason, it might be advisable to request an ethical approval anyway before the start of the project from the relevant ethics committee within your institution.

If you checked box 2, the intended collaboration must be submitted to the Committee on Human Rights Policy and Dual-Use Research. In order to prevent benefiting from human rights violations, collaborations with external partners are subject to a human rights impact assessment. Check our website in [Dutch](https://www.ugent.be/nl/univgent/waarvoor-staat-ugent/mensenrechten/overzicht.htm) or [English](https://www.ugent.be/en/ghentuniv/principles/human-rights/overview.htm) for more information.

## Environment & health and safety

|  |  |
| --- | --- |
|  | YES? |
| 1. Does your research involve the use of elements (chemical, physical, sound, …) that may cause harm to the environment (water, air, soil, …), or to animals or plants? |  |
| 1. Does your research involve the use of elements (chemical, physical, sound, …) that may cause harm to humans, including research staff and their co-workers? |  |
| 1. Is (part of) your research carried out within protected areas? |  |
| 1. Do the proposed experiments make use of GMOs or pathogens? |  |
| 1. Do the proposed experiments make use of activities, installations or products that need to be covered by permits (narcotic drugs and precursors, hormonal substances, explosives and precursors, cyanides, ozone-depleting substances, ionizing radiation, radioactive substances, soils/animals/animal parts and by-products/plants from third countries, …)? |  |

If you checked the box at questions 4 and/or 5, please ensure that you comply with the applicable legislations and guidelines regarding the environment, health and safety.

For question 4, an attestation concerning biosafety is required. See our [Dutch webpage](https://www.ugent.be/intranet/nl/op-het-werk/milieu/) and [milieu@ugent.be](mailto:milieu@ugent.be).

For question 5, different types of permits or attestations or a compulsory notification may be required.

- Narcotic drugs and precursors, hormonal substances, explosive compounds, ozone-depleting substances, soils/animals/animal parts and by-products/plants from third countries: see our [Dutch webpage](https://www.ugent.be/intranet/nl/op-het-werk/milieu/) and [milieu@ugent.be](mailto:milieu@ugent.be).

- Cyanides and prohibited substances: see our [Dutch webpage](https://www.ugent.be/intranet/en/human-resources/health-safety) and [veiligheid@ugent.be](mailto:veiligheid@ugent.be).

- Ionizing radiation and radioactive substances: see our [Dutch webpage](https://www.ugent.be/intranet/nl/op-het-werk/welzijn/straling) and [straling@ugent.be](mailto:straling@ugent.be).

## Other ethics issues

Your research may raise new ethical issues and concerns that are currently not (fully) covered by this ethics checklist (e.g., new developments in the fields of neurobiology, man-machine interaction, developments in nanotechnology, genetic enhancement, the creation of androids and cyborgs, Artificial Intelligence, etc.).

|  |  |
| --- | --- |
|  | YES? |
| 1. Are there any other issues that should be taken into consideration? |  |

If you checked the box, please specify: ………………………………………………………………………..

Please note that these issues not always trigger the obligation to request ethical approval. However, it is important to keep in mind that the journal in which you want to publish the results of your research might ask you to submit an ethical approval. For this reason, it might be advisable to request ethical approval anyway before the start of the project from the relevant ethics committee within your institution.

## Concluding questions

Please indicate which of the following situations apply to your research.

|  |  |
| --- | --- |
| 1. I confirm that none of the issues above apply to my proposal. |  |
| 1. I confirm that some ethics issues apply to my proposal and I will adhere to all relevant legislation and institutional policies. |  |
| 1. I confirm that for some of the issues an ethical approval is required for the start of my project. I will thus ensure submission of my proposal to the competent research ethics committee of the institution.    1. Please specify which ethics committee(s) will deal with your application:   …………………………………………………………………………………………… |  |