ETHICS QUESTIONNAIRE

Name of the promotor:

Title of the proposal/project:

A. INTRODUCTION

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

Researchers must reflect on the ethical aspects of their proposal and identify any ethical issues in the ethics questionnaire (**part B**). The actual questionnaire is followed by the declaration on honour (**part C**).

Sometimes there is a legal obligation to submit the project proposal to an ethics committee. This is made clear in the questionnaire. However, researchers may also submit their proposal to an ethics committee for an ethical approval if there is no legal obligation, e.g., when a journal requests an ethical approval. For further information, check our website in Dutch or English. A dedicated research tip informs you on what is requested when specific ethics issues apply, and provides further background information.

Even if no ethical issues apply to your proposal, you must always complete **part C** of the questionnaire (**Declaration on honour**).

B. QUESTIONNAIRE

1. Human embryos and foetuses

	YES?
1. Does your research involve human Embryonic Stem Cells (hESCs)?	☐
a. Will the hESCs be directly derived from embryos within this project? b. Are the hESCs previously established cell lines?	☐ ☐
2. Does your research involve the use of human embryos?	☐
3. 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 additional approval by the Federal Commission for Medical and Scientific Research on Embryos in Vitro (FCE).

2. Humans

	YES?
1. Does your research involve human participants?	☐
a. Are they volunteers for social or human sciences research?	☐
b. Are they persons unable to give informed consent (including children / minors)?	☐
c. Are they vulnerable individuals or groups?	☐
d. Are they children / minors?	☐
e. Are they patients?	☐
f. 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.

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.

3. Human cells and tissues

	YES?
Does your research involve human cells or tissues (other than from human embryos/foetuses)?	☐
a. Are the human cells or tissues obtained from commercial sources? b. Do they originate from another laboratory/institution/biobank? c. Were they produced or collected by you during previous research activities? d. 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.

4. Personal data

	YES?
Does your research involve collecting and/or processing of personal data?	☐

If you checked the box, the EU General Data Protection Regulation (GDPR) requires that all personal data processing activities are registered in the GDPR register of each institution where the processing takes place before the start of the processing. At UGent, this registration should be done in dmponline.be. Check our website for more information on how to register your personal data processing activities.

5. Animals

	YES?
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)?	☐
a. Are they non-human primates? b. Are they genetically modified animals? c. Are they cloned farm animals? d. Are they endangered species?	☐ ☐ ☐ ☐

In case you checked box a, you must have obtained an ethics approval at the time of submitting your proposal for funding. In case you checked box b, c or 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 or English for more information.

6. Access and Benefit-Sharing and the Nagoya Protocol

	YES?
Does your research involve genetic (biological) resources and/or traditional knowledge associated with genetic resources, that are in scope of the Nagoya Protocol and/or the related EU Regulation 511/2014? → Name of the country/ies of origin:	☐

Usually, you must obtain a 'Prior Informed Consent' (PIC) from the Competent National Authority 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 in Dutch or English for more information.

7. International collaboration

	YES?
1. Do you plan to use local resources (e.g., animal and/or human tissue samples, genetic material including that captured by question 6, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)? → Name of country/ies:	☐
2. Do you plan to import/export any material from/to other countries? → Name of country/ies:	☐
3. Could the situation in the country put the researchers and/or the individuals taking part in the research at risk?	☐

If you checked any of the boxes, please take into account the applicable legislation and guidelines regarding international transportation, cooperation and precautionary safety measures such as risk analyses.

8. Dual-use and military applications

	YES?
1. Does your research have the potential for military applications?	☐
2. Does your research involve dual-use items in the sense of EU 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 or English for more information.

Not every dual-use research triggers the obligation to request an ethical approval. However, you must inform the Dual Use Contact Point of your dual-use research using the Dual-Use Notification Form. 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.

9. Misuse and human rights

	YES?
1. Does your research have the potential for misuse of the research results?	☐
2. 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 or English for more information.

10. Environment and health & 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?	☐
2. Does your research involve the use of elements (chemical, physical, sound, …) that may cause harm to humans, including research staff and their co-workers?	☐
3. Is (part of) your research carried out within protected areas?	☐
4. Do the proposed experiments make use of GMOs or pathogens?	☐
5. 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 and 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 and milieu@ugent.be.
- Cyanides and prohibited substances: see our Dutch webpage and veiligheid@ugent.be.
- Ionizing radiation and radioactive substances: see our Dutch webpage and straling@ugent.be.

11. 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?
Are there any other issues that should be taken into consideration?	☐

If you checked the box, please specify:

Please note that these issues do not always trigger the obligation to request an 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.

C. DECLARATION ON HONOUR

Please confirm which of the following situations apply to your research (multiple answers are possible). It is required to at least answer either question 1 or 2.

1. I declare on honour that **none of the ethical issues** in part B of the questionnaire **apply to my proposal**.	☐
2. I declare on honour that **one or more of the ethical issues** in part B of the questionnaire do **apply to my proposal** and I commit to adhere to all relevant legislation, regulations and institutional guidelines and policies.	☐
3. I declare that for one or more ethical issues in part B of the questionnaire **an ethical approval is required**. I declare on honour that **I will submit my project proposal** in due time to the competent research **ethics committee(s)**. Please indicate which ethics committee(s) will deal with your application: ☐ Medical Ethics Committee ☐ Federal Commission for Embryos ☐ Ethics Committee for Animal Testing of the Faculty of Veterinary Sciences, also competent for the Faculty of Bioscience Engineering ☐ Ethics Committee for Animal Testing of the Faculty of Medicine and Health Sciences, also competent for the Faculty of Pharmaceutical Sciences ☐ Ethics Committee for Animal Testing of the Faculty of Sciences and the VIB ☐ Committee on Human Rights Policy and Dual-use Research ☐ Ethics Committee of the Faculty of Arts and Philosophy ☐ Ethics Committee of the Faculty of Engineering and Architecture ☐ Ethics Committee of the Faculty of Law and Criminology ☐ Ethics Committee of the Faculty of Economics and Business Administration ☐ Ethics Committee of the Faculty of Psychology and Educational Sciences ☐ Ethics Committee of the Faculty of Political and Social Sciences	☐