ETHICS QUESTIONNAIRE

Name of promotor:

Title of project:

Start date of project:

A. QUESTIONNAIRE

Please reflect on the ethical aspects of your proposal and complete the ethics questionnaire. For detailed information, consult this research tip. Even if no ethical issues apply to your proposal, you must complete the questionnaire.

1. HUMAN EMBRYOS

	YES	NO
Does your research involve human Embryonic Stem Cells (hESCs)? *	☐	☐
If yes, will they be directly derived from embryos within this project?	☐	☐
If yes, are they previously established cell lines?	☐	☐
Does your research involve the use of human embryos? * **	☐	☐

* If yes, 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 ethics approval for the project.

** If yes, your research project requires additional approval by the Federal Commission for Medical and Scientific Research on Embryos in Vitro.

2. HUMANS

	YES	NO
Does your research involve human participants?	☐	☐
If yes, are they volunteers for nonmedical studies (e.g. social or human sciences research)?	☐	☐
*If yes, are they healthy volunteers for medical studies? **	☐	☐
*If yes, are they patients for medical studies? **	☐	☐
If yes, are they potentially vulnerable individuals or groups? [1]	☐	☐
If yes, are they children / minors? [1]	☐	☐
If yes, are they other persons unable to give informed consent? [1]	☐	☐
Does your research involve interventions (physical, also including imaging technology, behavioural treatments, etc.) on the study participants? *	☐	☐
If yes, does it involve invasive techniques?	☐	☐
If yes, does it involve collection of biological samples?	☐	☐

* If yes, 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 ethics approval for the project.

[1] Notice on human participants or personal data: while not every research involving human participants or personal data triggers the obligation to request an ethics approval, it might be advisable to request an ethics approval from a competent ethics committee anyway before the start of your project. Also, the journal in which you want to publish the results of your research might ask you to provide proof of an ethics approval.

3. HUMAN CELLS AND TISSUES

	YES	NO
Does your research involve the use of human cells or tissues (not covered by section 1, i.e. other than human embryonic tissue and hESCs)? *	☐	☐
If yes, are they human embryonic or foetal cells or tissues?	☐	☐
If yes, are they obtained from commercial sources?	☐	☐
If yes, are they obtained from another laboratory/institution/biobank?	☐	☐
If yes, were they obtained by you during previous research activities?	☐	☐
If yes, are they obtained by you as part of this project?	☐	☐

* If yes, 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 ethics approval for the project.

4. PERSONAL DATA

	YES	NO
Does your research involve collecting or processing of personal data? [1] *	☐	☐
If yes, does it involve the collection and/or processing of special categories of personal data? [2]	☐	☐
If yes, does it involve profiling, systematic monitoring of individuals, or large-scale processing of special categories of data, or intrusive methods of data processing (such as surveillance, geolocation tracking etc.)? [2]	☐	☐
If yes, does your research involve further processing of previously collected personal data (including use of pre-existing data sets or sources or merging existing data sets)? [2]	☐	☐
If yes, does it involves the processing of personal data related to criminal convictions or offences? [2]	☐	☐
Does your research involve international import/export of personal data? [1] *	☐	☐
If yes, do you plan to export personal data from the EU to non-EU countries? [3]	☐	☐
If yes, do you plan to import personal data from non-EU countries into the EU or allocate personal data from a non-EU country to another non-EU country? [3]	☐	☐

* If yes, your research involves collecting or processing personal data, the EU General Data Protection Regulation (GDPR) requires that all processing activities are registered in the GDPR register of each institution where the processing takes place before the start of the processing. At Ghent University, this registration should be done in dmponline.be. Check this research tip for more information on how to register your processing activities.

[1] Notice on human participants or personal data: while not every research involving human participants or personal data triggers the obligation to request an ethics approval, it might be advisable to request an ethics approval from a competent ethics committee anyway before the start of your project. Also, the journal in which you want to publish the results of your research might ask you to provide proof of an ethics approval.

[2] Notice on high risk personal data: you might collect/process high risk personal data and you might need to take additional safety measures.

[3] Notice on import or export of personal data: you are transferring personal data to or from non-EU countries where the GDPR does not apply. Check this research tip for the additional measures you have to take to safeguard the privacy of the data subjects.

5. ANIMALS

	YES	NO
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)? *	☐	☐
If yes, are they non-human primates?	☐	☐
If yes, are they genetically modified animals?	☐	☐
If yes, are they cloned farm animals?	☐	☐
If yes, are they endangered species?	☐	☐
If yes, please specify where the research will take place (choose one answer only).		
☐ *Faculty of Bioscience Engineering* [1]		
☐ *Faculty of Medicine and Health Sciences* [2]		
☐ *Faculty of Pharmaceutical Sciences* [2]		
☐ *Faculty of Sciences* [3]		
☐ *Faculty of Veterinary Medicine* [1]		
☐ *VIB-UGent Center for Medical Biotechnology* [3]		

* If yes, you must submit your proposal to the competent Committee for Animal Research and Testing as soon as your application has been approved for funding. The project can only start when the committee has formally given an ethics approval for the project.

Competent ethics committees:

1: Ethics Committee for Animal Research and Testing of the Faculty of Veterinary Sciences
2: Ethics Committee for Animal Research and testing of the Faculty of Medicine and Health Sciences
3: Ethics Committee for Animal Testing of the Faculty of Sciences and the VIB

6. INTERNATIONAL COLLABORATION, EXPLOITATION AND ETHICS DUMPING

	YES	NO
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:		
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? [1,2]	☐	☐
Name of country/ies:		
Will some of the activities be carried out in non-EU countries? [1]	☐	☐
If yes, do the activities undertaken in the country/ies raise potential ethics issues?	☐	☐
If yes, could the situation in the country/ies put the individuals taking part in the activity at risk?	☐	☐
Name of country/ies:		
Do you plan to import any material from non-EU countries? [1]	☐	☐
If yes, specify material and country/ies:		
Do you plan to export any material to non-EU countries? [1]	☐	☐
If yes, specify material and country/ies:		

[1] Notice on international collaboration: please take into account the applicable legislation and guidelines regarding international transportation, cooperation and precautionary safety measures such as risk analyses.

[2] Notice on the Nagoya Protocol: if your research is in scope of the Nagoya Protocol, 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 sometimes be negotiated and registered in 'Mutually Agreed Terms' (MAT). Check this webpage for more information.

7. DUAL-USE AND MILITARY APPLICATIONS

	YES	NO
Could your research or the research results (goods, software, technology, knowledge) be useful for military purposes, or do you work with a partner who develops technology for military end-use? *	☐	☐
Does your research involve dual-use items, software or technology in the sense of Regulation (EU) 2021/821?	☐	☐
*If yes, will these items, software or technology be shared with entities outside of the EU? **	☐	☐

* If yes, you must submit your proposal to the Committee on Human Rights Policy and Dual-Use Research, as soon as your application has been approved for funding. The project can only start when the committee has formally given an ethics approval of the project.

** If yes, a dual-use export license is required prior to sharing the materials, technology, or research results. You must contact the Dual-Use Contact Point to apply for an export license.

8. MISUSE AND HUMAN RIGHTS

	YES	NO
Could the research (results) be used for terrorist or criminal activities, or compromise the safety of humans, animals or the environment? *	☐	☐
Could the research (results) be used to violate human rights, or might the project partner be involved in human rights violations? *	☐	☐

* If yes, you must submit your proposal to the Committee on Human Rights Policy and Dual-Use Research, as soon as your application has been approved for funding. The project can only start when the committee has formally given an ethics approval of the project.

9. ENVIRONMENT AND HEALTH & SAFETY

	YES	NO
Does your research involve the use of substances or processes that may cause harm to the environment, animals or plants (during the implementation of the activity or as a result or possible impact of the use of its results)?	☐	☐
Does your research involve the use substances or processes that may cause harm to humans, including research staff and their co-workers (during the implementation of the activity or as a result or possible impact of the use of its results)?	☐	☐
Could your research, or the results that can reasonably be expected, cause harm to the climate, or hamper climate adaptation?	☐	☐
Is (part of) your research carried out within protected areas?	☐	☐
Does your research involve the use of genetically modified organisms or pathogens? [1,2]	☐	☐
Does your research involve the 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, …)? [1,3]	☐	☐

[1] Notice on environment, health and safety: please ensure to comply with all applicable legislations and guidelines.

[2] Notice on genetically modified organisms and pathogens: an attestation concerning biosafety is required. See this (Dutch) webpage and milieu@ugent.be.

[3] Notice on certain activities, installations or products: 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 this (Dutch) webpage and milieu@ugent.be.
- Cyanides and prohibited substances: see this (Dutch) webpageand veiligheid@ugent.be.
- Ionizing radiation and radioactive substances: see this (Dutch) webpage and straling@ugent.be.

10. OTHER ETHICAL ISSUES

	YES	NO
Are there any other issues that should be taken into consideration? [1]	☐	☐
If yes, please specify:		

[1] Notice on other ethical issues: please note that these other ethical issues do not always trigger the obligation to request an ethics 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 ethics approval. For this reason, it might be advisable to request an ethics approval anyway before the start of the project from a relevant ethics committee.

B. CONCLUSIONS

Please review the list of ethics committees and legal obligations below.

Tick the ethics committees that you plan to submit your proposal to[1]. Some committee approvals might be legally or institutionally required. This is indicated by asterisks (*) in the relevant questions in the questionnaire above. You can find the contact details of the Ghent University ethics committees on the research ethics webpage.

In case of legal obligations related to GDPR[1] and/or a dual-use export license[2], also indicated by asterisks above, please tick the relevant box(es) as well.

- ☐ Committee for Medical Ethics
- ☐ Federal Commission for Embryos
- ☐ Ethics Committee for Animal Research and Testing of the Faculty of Veterinary Sciences
- ☐ Ethics Committee for Animal Research and testing of the Faculty of Medicine and Health 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 Economics and Business Administration
- ☐ Ethics Committee of the Faculty of Engineering and Architecture
- ☐ Ethics Committee of the Faculty of Law and Criminology
- ☐ Ethics Committee of the Faculty of Political and Social Sciences
- ☐ Ethics Committee of the Faculty of Psychology and Educational Sciences

- ☐ Registration of processing of personal data in GDPR register of Ghent University
- ☐ Application for a dual-use export license

[1] Deadlines for submission of ethics committee approvals and GDPR registration are the start date of the project. Note that the deadline for submission of an ethics approval can be adjusted if needed and permitted, when the project has been granted.

[2] Deadline of the application for a dual-use export licence: before sharing the items outside of the EU.