

Last name: _____

First name: _____

Ethics Form

Please complete the following in-depth ethics self-assessment questionnaire on your research project. Please tick (X) the appropriate box and provide further information if required:

1. HUMAN EMBRYOS/FOETUSES	Yes	No	If yes, please indicate page in your research proposal	If yes, please describe how you will deal with this issue. For guidelines on what to include here, please refer to section 1 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
Does your research involve Human Embryonic Stem Cells (hESCs)?				
Will they be directly derived from embryos within this project?				
Are they previously established cells lines?				
Does your research involve the use of human embryos?				
Does your research involve the use of human fetal tissues / cells?				
<i>For guidelines on what to include here, please refer to section 1 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i>				

2. HUMANS	Yes	No	If yes, please indicate page in your research proposal	If yes, please describe how you will handle this issue. For guidelines on what to include here, please refer to section 2 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
Does your research involve human participants?				
Are they volunteers for social or human sciences research?				
Are they persons unable to give informed consent?				

Are they vulnerable individuals or groups?				
Are they children/minors?				
Are they patients?				

Are they healthy volunteers for medical studies?				
Does your research involve physical interventions on the study participants?				
Does it involve invasive techniques?				
Does it involve collection of biological samples?				
Does your research involve processing of genetic information?				

For guidelines on what to include here, please refer to [section 2](#) of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.

3. HUMAN CELLS / TISSUES	Yes	No	If yes, please indicate page in your research proposal	If yes, please describe how you will handle this issue. For guidelines on what to include here, please refer to section 3 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
Does your research involve human cells or tissues (other than from Human Embryos/Fetuses, i.e. section 1)?				
Are they available commercially?				
Are they obtained within this project?				
Are they obtained within another project?				
Are they deposited in a biobank?				
<p><i>For guidelines on what to include here, please refer to section 3 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i></p>				

4. PERSONAL DATA	Yes	No	If yes, please indicate page in your research proposal	If yes, please describe how you will handle this issue. For more info on what to include here, please refer to section 4 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
Does your research involve personal data collection and/or processing?				
Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?				
Does it involve processing of genetic information?				

Does it involve tracking or observation of participants?				
Does your research involve further processing of previously collected personal data (secondary use)?				
<i>For more info on what to include here, please refer to section 4 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i>				

5. ANIMALS	Yes	No	If yes, please indicate page in your research proposal	If yes, please describe how you will handle this issue. For more info on what to include here, please refer to section 5 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
Does your research involve animals?				
Are they vertebrates?				
Are they non-human primates?				
Are they genetically modified?				
Are they cloned farm animals?				
Are they endangered species?				
<i>For more info on what to include here, please refer to section 5 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i>				

6. THIRD COUNTRIES (NON-EU COUNTRIES)	Yes	No	If yes, please indicate page in your research proposal	If yes, please name the countries involved and describe how you will handle this issue. For more info on what to include here, please refer to section 6 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
Does your research involve non-EU countries?				
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.)?				
Do you plan to import any material from non-EU countries into the EU? <i>For data imports, please fill in also section 4.</i> <i>For imports concerning human cells or tissues, fill in also section 3.</i>				
Do you plan to export any material from the EU to non-EU countries? <i>For data exports, please fill in also section 4.</i> <i>For exports concerning human cells or tissues, fill in also section 3.</i>				

If your research involves low and/or lower middle income countries, are benefits-sharing measures foreseen?				
Could the situation in the country put the individuals taking part in the research at risk?				
<i>For more info on what to include here, please refer to section 6 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i>				

7. ENVIRONMENT, HEALTH & SAFETY	Yes	No	If yes, please indicate page in your research proposal	If yes, please describe how you will handle this issue. For more info on what to include here, please refer to section 7 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
Does your research involve the use of elements that may cause harm to the environment, to animals or plants? <i>For research involving animal experiments, please fill in also section 5.</i>				
Does your research deal with endangered fauna and/or flora and/or protected areas?				
Does your research involve the use of elements that may cause harm to humans, including research staff? <i>For research involving human participants, please fill in also section 2.</i>				
<p><i>For more info on what to include here, please refer to section 7 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i></p>				

8. DUAL USE	Yes	No	If yes, please indicate page in your research proposal	If yes, please describe how you will handle this issue. For more info on what to include here, please refer to section 8 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
Does your research have the potential for military applications?				
<p><i>For more info on what to include here, please refer to section 8 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i></p>				

9. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS	Yes	No	If yes, please indicate page in your research proposal	If yes, please describe how you will handle this issue. For more info on what to include here, please refer to section 9 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
<p>Could your research raise concerns regarding the exclusive focus on civil applications?</p>				
<p><i>For more info on what to include here, please refer to section 9 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i></p>				

10. MISUSE	Yes	No	If yes, please indicate page in your research proposal	If yes, please describe how you will handle this issue. For more info on what to include here, please refer to section 10 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
<p>Does your research have the potential for malevolent/criminal/terrorist abuse?</p>				
<p><i>For more info on what to include here, please refer to section 10 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i></p>				

11. OTHER ETHICS ISSUES	Yes	No	If yes, please indicate page in your research proposal	If yes, please specify, and describe how you will handle this/these issue/s. For more info on what to include here, please refer to section 11 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.
Are there any other ethics issues that should be taken into consideration?				
<i>For more info on what to include here, please refer to section 11 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i>				

12. CONFIRMATION ETHICS SELF-ASSESSMENT	Yes	No	
I confirm that I have taken into account all ethics issues described above and that I will adhere to the highest possible ethics standards when conducting my research			