

Last name: _____

BIGSSS Program: _____

First name: _____

Date: _____

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? | | | | |

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|--|--|--|--|--|
| 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? | | | | |
| <i>For guidelines on what to include here, please refer to section 3 of the "Guidance EU Ethics Self-Assessment BIGSSS-departs" document.</i> | | | | |

| 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 | | | |