

## ETHICS SELF-ASSESSMENT GUIDE

Please use this list as guidance for identifying the main ethics issues concerning the Research Unit's activities

### ETHICS ISSUE 1: HUMAN EMBRYOS/FOETUS

1. Do the research activities of the Research Unit involve Human Embryonic Stem Cells (hESCs)?
  - 1.1. If yes, will they be directly derived from embryos within the research activity of the Research Unit?
  - 1.2. 1.2 If yes, are they previously established cells lines?
2. Do the research activities of the Research Unit involve the use of human embryos?
  - 2.1. If yes, will the research activities of the Research Unit lead to their destruction?
3. Do the research activities of the Research Unit involve the use of human foetal tissues/cells?

### ETHICS ISSUE 2: HUMANS

1. Do the research activities of the Research Unit involve human participants?
  - 1.1. If yes, are they volunteers for social or human sciences research?
  - 1.2. If yes, are they persons unable to give informed consent?
  - 1.3. If yes, are they vulnerable individuals or groups (children, patients, discriminated people, minorities, persons unable to give consent, people of dissenting, immigrant or minority communities, sex workers, etc.)?
  - 1.4. If yes, are they children/minors?
  - 1.5. If yes, are they patients?
  - 1.6. If yes, are they healthy volunteers for medical studies?
2. Do the research activities of the Research Unit involve physical interventions on the study participants?
  - 2.1. If yes, does it involve invasive techniques?

### ETHICS ISSUE 3: HUMANS CELLS/TISSUES

1. Do the research activities of the Research Unit involve human cells or tissues? (other than from Human Embryos/Foetuses, see ethics issue 1)
  - 1.1. If yes, are they available commercially?
  - 1.2. If yes, are they obtained within the research activity of the Research Unit?
  - 1.3. If yes, are they obtained from another project, laboratory or institution?
  - 1.4. If yes, are they obtained from biobank?

#### **ETHICS ISSUE 4: PROTECTION OF PERSONAL DATA**

1. Do the research activities of the Research Unit involve personal data collection and/or processing?
  - 1.1. If yes, does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?
  - 1.2. If yes, does it involve processing of genetic information?
  - 1.3. If yes, does it involve tracking or observation of participants?
2. Do the research activities of the Research Unit involve further processing of previously collected personal data (secondary use)?

#### **ETHICS ISSUE 5: ANIMALS**

1. Do the research activities of the Research Unit involve animals?
  - 1.1. If yes, are they vertebrates?
  - 1.2. If yes, are they non-human primates (NHPs)?
  - 1.3. If yes, are they genetically modified?
  - 1.4. If yes, are they cloned farm animals?
  - 1.5. If yes, are they endangered species?

#### **ETHICS ISSUE 6: THIRD COUNTRIES**

1. In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?
2. Is it planned 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.)?
3. Is it planned to import any material – including personal data – from non-EU countries into the EU?
4. Is it planned to export any material, including personal data –from the EU to non-EU countries?
5. In case the research activities of the Research Unit involve low and/or lower-middle income countries, are any benefit-sharing actions planned?
6. Could the situation in the country put the individuals taking part in the research at risk?

#### **ETHICS ISSUE 7: ENVIRONMENT & HEALTH AND SAFETY**

1. Do the research activities of the Research Unit involve the use of elements that may cause harm to the environment, to animals or plants?
2. Do the research activities of the Research Unit deal with endangered fauna and/or flora/protected areas?
3. Do the research activities of the Research Unit involve the use of elements that may cause harm to humans, including research staff?

#### **ETHICS ISSUE 8: DUAL USE**

1. Do the research activities of the Research Unit involve dual-use items (goods, software, technology that can be used for both civilian and military applications and/or can contribute to the proliferation of weapons of mass destruction) in the sense of Regulation 428 / 2009, or other items for which an authorisation is required?

#### **ETHICS ISSUE 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS**

1. Could the research activities of the Research Unit raise concerns regarding the exclusive focus on civil applications?

#### **ETHICS ISSUE 10: MISUSE**

1. Do the research activities of the Research Unit have a potential for misuse (potential for malevolent/criminal/terrorist abuse) of research results?