H2020 RISE

Ethics issues

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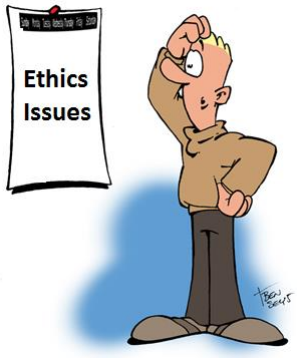
European Commission

1. **What Raises Ethics Issues?**

2. **Actions After the GAP**
   - Ethics Approvals
   - Data Protection Approvals
   - Informed Consents
   - Authorisations
   - Material Transfer with TC
   - Ethics Adviser/Advisory Board
   - Ethics Section of Reports
   - Ethics Checks

3. **Legal Aspects**

4. **Additional Guidelines**



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What Raises Ethics Issues? 1

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Protection of Personal Data

- ✓ When personal data is collected or processed
- ✓ Regardless of the method: interviews, questionnaires, etc.
- ✓ "*Personal data*" means any information, which relates to an identified or identifiable natural person

Research with Humans

- ✓ *Examples*: Collection of biological samples, Collection of personal data, Medical interventions, Interviews, Secondary use of information provided for other purposes, etc.
- ✓ Some issues are linked to Protection of Personal Data

What Raises Ethics Issues? 2

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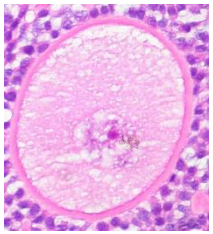
Research with Human Embryos/Foetus

Must be identified at proposal stage



- ✓ Includes research involving Human Embryonic Stem cells
- ✓ Activities prohibited in a MS can't be funded in that MS and activities prohibited in all the Member States can't be funded.
- ✓ Some research activities are not allowed:
  - ➢ Human cloning for reproductive purposes
  - ➢ Heritable genetic modification of human beings
  - ➢ Create human embryos just for research or stem cell procurement

Research with Humans Cells/Tissues

- ✓ Obtained from commercial sources
- ✓ Obtained from another institution or a biobank
- ✓ Produced or collected by you during previous research activities
- ✓ Produced or collected by you as part of this research project

What Raises Ethics Issues? 3

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Research with Animals

- ✓ You must favour alternatives to animal use and implement the principles of *replacement*, *reduction* and *refinement* "3Rs"

Environmental Protection and Safety

- ✓ Research that may have a negative impact on the environment or the health and safety of the researchers involved
- ✓ Due to the experimental design of the research itself or undesirable side-effects of the technologies used

Non-EU Member State Participation

- ✓ Research activities are carried out in a Third Country
- ✓ Participants or resources come from a Third Country
- ✓ Material is imported/exported from/to a Third Country

No funding for activities carried out outside the EU if prohibited in all MS

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What Raises Ethics Issues? 4

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Dual Use

- ✓ When the research also has potential for military applications
- ✓ Only research that has an exclusive focus on civil applications can be funded (this does not exclude military participants)

Misuse

- ✓ Biological, chemical, radiological and nuclear sensitive materials
- ✓ Research that could impact on human rights
- ✓ Research that has other potential for terrorist or criminal abuse

Other

- ✓ New ethics issues and concerns currently not covered

Please contact your project officer immediately if ethics issues arise unexpectedly during your research

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Main Possible Pending Issues

- In principle most Ethics Issues were addressed during the GAP

- The main points that might still require attention after the GAP are:

✓**Ethics Approvals**
✓**Data Protection Approvals**
✓**Informed Consent Templates**
✓**Authorisations**
✓**Material Transfer with TC**
✓**Ethics Adviser/Advisory Board**
✓**Ethics Section of Reports**
✓**Ethics Checks**

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Ethics Approvals

- Main Ethics Issues concerned:
  - ✓**Research with hESC (Embryos/Foetus)**
  - ✓**Research with Humans**
  - ✓**Research with Human Tissues/Cells**
  - ✓**Misuse**
- To be issued by the competent authority (local, regional or national level, e.g. ethics committee of your university)
- Must be provided **before the start of the relevant WP**(s)
- If the document has an expiration date, the entire WP duration must be covered (send renewals if needed)
- Must be **project specific** (indicate *title*, *acronym*, *number*)
- All participants concerned must provide one (clearly indicate which participants are involved in the activities and which are not)

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Data Protection Approvals

- Main Ethics Issues concerned:
  - ✓**Protection of Personal Data**
  - ✓**Research with Humans**
- You must provide :
  - ✓Confirmation by the competent **Institutional Data Protection Officer**

  and/or
  - ✓Authorization by the **National Data Protection Authority**

  (*which ever applies according to the Data Protection Directive and national law*)
- Must be provided **before the start of the relevant WP**(s)
- Must be **project specific** (indicate *title*, *acronym*, *number*)
- All participants concerned must provide one (clearly indicate which participants are involved in the activities and which are not)

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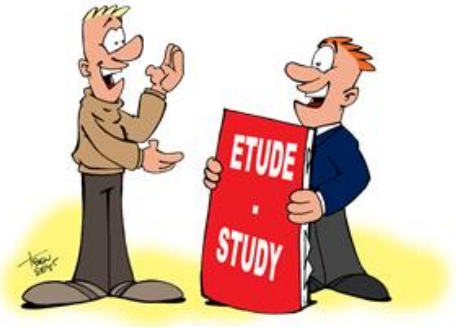
Informed Consent Templates



- Main Ethics Issues concerned:
  - ✓**Protection of Personal Data**
  - ✓**Research with Humans**
  - ✓**Research with hESC (Embryos/Foetus)**
  - ✓**Research with Human Tissues/Cells**
- Must be in a language understandable by the subjects
- Must be provided **before the start of the relevant WP**(s)
- All participants concerned must provide one (clearly indicate which participants are involved in the activities and which are not)

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Authorisations

- Main Ethics Issues concerned:
  - ✓**Research with Human Tissues/Cells**
  - ✓**Research with Animals**
  - ✓**Environmental Protection and Safety**
  - ✓**Misuse**
- To be issued by the competent authority (local, regional or national level, e.g. ethical committee of your university)
- Must be provided **before the start of the relevant WP**(s)
- If the document has an expiration date, the entire WP duration must be covered (send renewals if needed)
- Must be **project specific** (indicate *title*, *acronym*, *number*)
- All participants concerned must provide one (clearly indicate which participants are involved in the activities and which are not)

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Material Transfer with TC

- Main Ethics Issues concerned:
  - ✓**Research with Human Tissues/Cells**
  - ✓**Protection of Personal Data**
  - ✓**Research with Animals**
  - ✓**Non-EU Member State Participation**

- In case of data, an agreement between the parties (MTA) and a specific authorisation by the MS National Data Protection Authority are needed (check country exception, e.g. *Safe Harbour* list for US).

- In case of biological material, copies of import/export licences are needed.

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Ethics Adviser/ Advisory Board

- Main Ethics Issues concerned:
  - ✓**All**
- The advisers **must be independent** (cannot work in the same institution)
- A report from the adviser/advisory board describing the handling of the ethics issues during the respective period must be annexed to each periodic report

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Ethics Section of Reports

- Main Ethics Issues concerned:
  - ✓**All**
- A specific section of the periodic and progress reports is dedicated to ethics
- Describe the management of the ethics issues during the implementation in this section

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Ethics Checks

- Main Ethics Issues concerned:
  - ✓ **All**
- EU services might implement some checks to the ethics part with the help of external experts
- Normally done with the experts in Brussels, but an onsite audit might also be done
- Feedback is provided to the coordinators if an action is needed following the check

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Important

- All research activities of RISE projects **must comply with EU and national law**

- Documents not in one of the EU official languages must be translated to English

H2020 Online Manual

- Information on Ethics Appraisal Procedure (e.g. ethics checks and audits)
- Guidance & Reference documents

http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

Additional Guidelines 2

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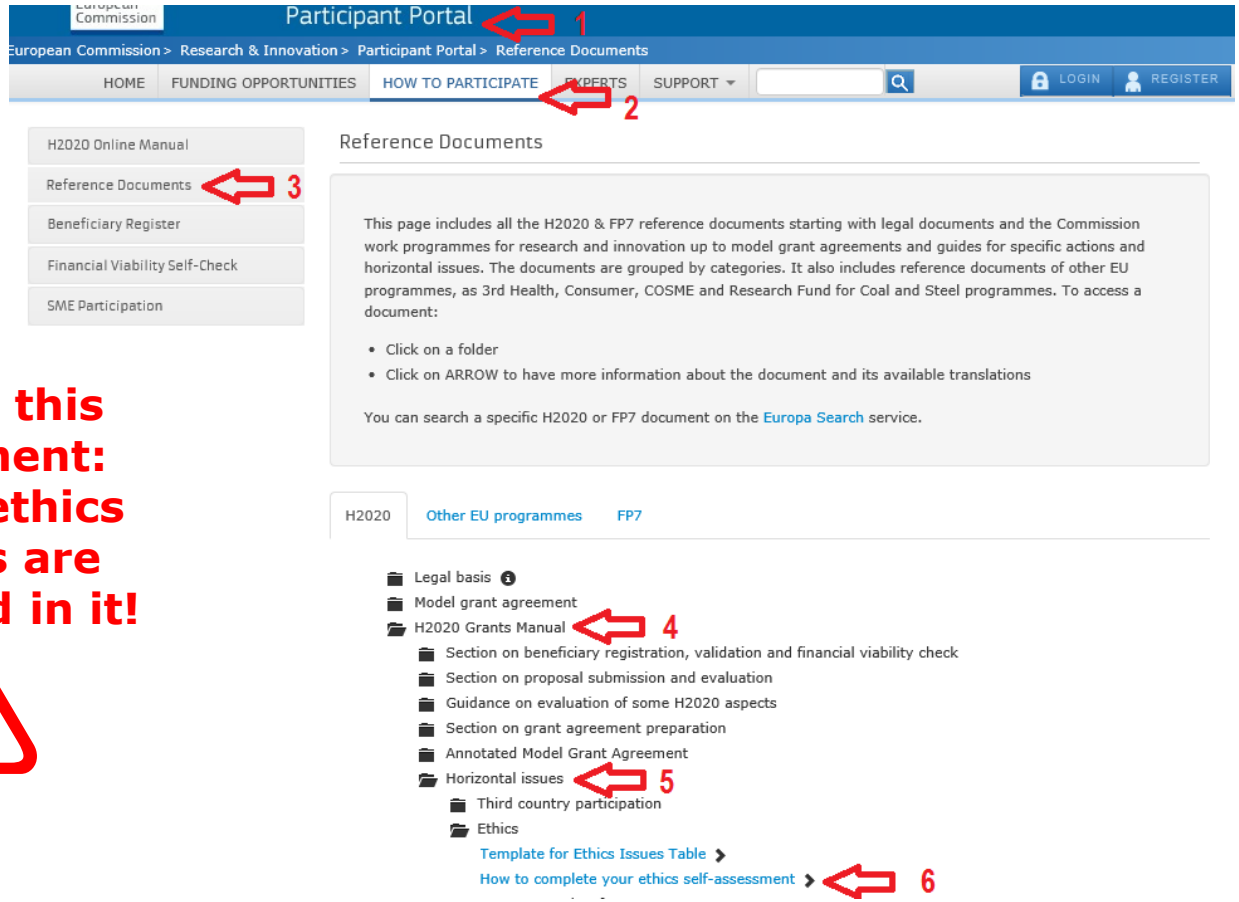
Ethics self-assessment guidance



Check this document: many ethics issues are clarified in it!

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

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Thank you for your attention

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