



H2020 RISE

Ethics issues

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Frederico Miranda
Project Officer

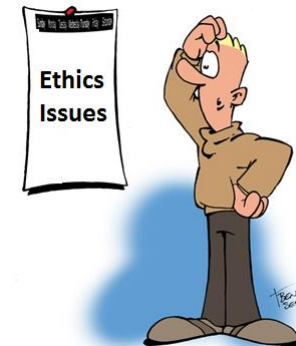
1. What Raises Ethics Issues?

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



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



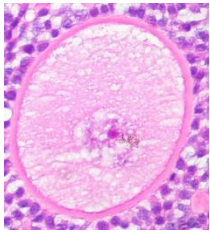
Research with Humans

- ✓ *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



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

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**

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

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**





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)



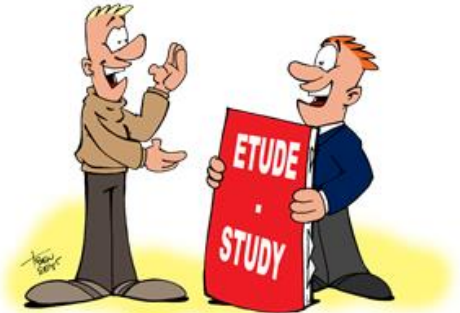
Data Protection Approvals



- 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)

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)





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)



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.



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



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

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

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

A screenshot of the "Participant Portal H2020 Online Manual" website. The page has a blue header with the European Commission logo and the text "RESEARCH & INNOVATION Participant Portal H2020 Online Manual". A left-hand navigation menu lists various sections like "My Area - User account & roles", "Grants", and "Applying for funding". The main content area shows a breadcrumb trail "> H2020 Online Manual > Cross-cutting issues >" followed by filter buttons for "International cooperation", "Ethics", and "Gender". Below this, there are buttons for "Links to regional policy" and "Social Sciences & Humanit". The main heading is "Ethics", followed by a paragraph explaining that ethics is an integral part of compliance for EU-funded activities. Below this is a section titled "Objectives" and another titled "Ethics Appraisal Procedure".

H2020 Online Manual

- My Area - User account & roles
 - Login with ECAS
 - Roles & access rights
 - Terms and Conditions of Use
- Grants
 - Applying for funding
 - Find a call
 - Horizon 2020 structure and budget
 - What you need to know about Horizon 2020 calls
 - Find partners or apply as individual
 - Register in the Beneficiary Register
 - Registration of your organisation
 - LEAR appointment
 - Validation of potential beneficiaries
 - Financial viability check
 - Data update
 - Certifications
 - Submit a proposal
 - Get prepared
 - Electronic proposal submission

> H2020 Online Manual > Cross-cutting issues >

International cooperation Ethics Gender

Links to regional policy Social Sciences & Humanit

Ethics

For all activities funded by the European Union, ethics is an integral part of compliance is seen as pivotal to achieve real research excellence. There is evaluation from the conceptual stage of the proposal not only to respect the quality of the research. Ethical research conduct implies the application of scientific research in all possible domains of research. The process to assess activities funded under Horizon 2020 is called the **Ethics Appraisal Procedure**

Objectives

In addition to the scientific evaluation focusing on the scientific merit, the impact, the Ethics Appraisal ensures that all research activities carried out are conducted in compliance with fundamental ethical principles.

Ethics Appraisal Procedure

The Ethics Appraisal Procedure concerns all activities funded in Horizon 2020 conducted before the start of the project, as well as the Ethics Checks and

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



Ethics self-assessment guidance

The screenshot shows the 'Participant Portal' interface. At the top, the breadcrumb trail is 'European Commission > Research & Innovation > Participant Portal > Reference Documents'. The navigation menu includes 'HOME', 'FUNDING OPPORTUNITIES', 'HOW TO PARTICIPATE', 'EXPERTS', and 'SUPPORT'. A search bar and 'LOGIN'/'REGISTER' buttons are also present. On the left, a sidebar menu lists 'H2020 Online Manual', 'Reference Documents', 'Beneficiary Register', 'Financial Viability Self-Check', and 'SME Participation'. The main content area is titled 'Reference Documents' and contains a paragraph of text and a list of bullet points. Below this, there are tabs for 'H2020', 'Other EU programmes', and 'FP7'. A tree view shows a hierarchy of folders: 'Legal basis', 'Model grant agreement', 'H2020 Grants Manual', 'Section on beneficiary registration, validation and financial viability check', 'Section on proposal submission and evaluation', 'Guidance on evaluation of some H2020 aspects', 'Section on grant agreement preparation', 'Annotated Model Grant Agreement', 'Horizontal issues', 'Third country participation', and 'Ethics'. Under 'Ethics', there are links for 'Template for Ethics Issues Table' and 'How to complete your ethics self-assessment'.

1. Participant Portal

2. HOW TO PARTICIPATE

3. Reference Documents

4. H2020 Grants Manual

5. Horizontal issues

6. How to complete your ethics self-assessment

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



European
Commission

Thank you for your attention



Research
Executive
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