Sapienza Università di Roma
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Ethical aspects of research and place of Social Sciences and Humanities (SSH) in addressing the Key Challenges

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Why Ethics Review?

Aims
- To protect the European Commission, the participants, and the researchers
- To maximize the positive impact of research results

Responding
- To the demands of the European citizens
- To the task of bringing research closer to the citizen

Risk
- Is central to research. It can not be eliminated. It can be reduced
HORIZON 2020: Legal Basis

➢ ARTICLE 18 – GRANT AGREEMENT

➢ The grant agreement shall, where appropriate, contain provisions ensuring the respect of ethical principles, including the establishment of an independent ethics board and the right of the Commission to carry out an ethics audit by independent experts.

➢ ARTICLE 23 - IMPLEMENTATION OF ACTIONS

➢ Participants shall comply with national legislation, regulations and ethical rules in the countries where the action will be carried out. Where appropriate, participants shall seek the approval of the relevant national or local ethics committees prior to the start of the action.
H2020: Legal Basis

➢ ARTICLE 34 – ETHICS
➢ The beneficiaries must carry out the action in compliance with:
  ➢ (a) ethical principles (including the highest standards of research integrity and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct)
  ➢ (b) applicable international, EU and national law.
➢ Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.
➢ The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications

➢ ARTICLE 39 — PROCESSING OF PERSONAL DATA
➢ The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).
Scientific Evaluation and Ethics Assessment

➢ Scientific evaluation

All proposals submitted to the Commission for funding following a call for proposals are evaluated by topical experts on their scientific merit.

➢ For proposals above quality threshold:

➢ an ethics screening and if necessary, an ethics assessment is carried out by independent ethics experts.
Ethics Process

➢ Ethics process
   Step 1: Ethics Screening
   Step 2: Ethics Review
   Step 3: Ethics Follow-up and Audit
Ethics Requirements

- Applicants are asked to consider:
  - Objectives and ethics (issue mainly in dual use research)
  - Methodology and ethics (a good scientific methodology needs to be also ethically sound)
  - Impact and ethics (utility and consequence)
  - Know the law; know who to ask: Timeframe for approvals
Some Common Problems in Applications

- **Clinical trials**: failure to justify human intervention from an ethical perspective, safeguard data protection, design of informed consent forms.
- **Third in particular** *developing countries*.
- **Animal welfare**.
- **Data protection and privacy**: codification, storage and anonymization of personal data.
- **Collection of private data**: how necessary is it?
Involvement in Research of Children and Vulnerable Persons

- Involvement of **children** is always a **major ethics issue**: failure to describe if a child obtains a real and direct **benefit**. If child is not directly benefitted, a **minimum risk** and minimum **burden** must be illustrated.

- **Vulnerable persons**: Illegal immigrants, prison populations, people with special needs...
H2020 Ethics Issues

1 - HUMAN EMBRYOS/FOETUSES
2 - HUMANS
3 - HUMAN CELLS / TISSUES
4 - PROTECTION OF PERSONAL DATA
5 - ANIMALS
6 - THIRD COUNTRIES = Non EU, non-associated
7 - ENVIRONMENTAL PROTECTION AND SAFETY
8 - DUAL USE
9 - MISUSE
10 - OTHER ETHICS ISSUES

Plus issues of research integrity: No Fabrication, No Falsification, no plagiarism or other research misconduct
Ethics Issues: THIRD COUNTRIES

➢ Applicable legislation:
   ➢ • Convention on Biological Diversity: http://www.cbd.int/
     and Nagoya Protocol: http://www.cbd.int/abs
   ➢ • Declaration of Helsinki: http://www.wma.net/en/30publications/10policies/b3/
   ➢ • low and/or lower middle income countries: http://www.oecd.org/development/stats/89483614.pdf
   ➢ • Commission decisions on the adequacy of the protection of personal data in third countries:

➢ Possible ethical issues:
   ➢ - the potential exploitation of research participants and/or local resources, mainly in developing countries
   ➢ - non-compliance with Horizon 2020 ethics rules
   ➢ - health and safety risks for researchers and staff

➢ Information to be reviewed: Details on
   ➢ - activities carried out in non-EU countries
   ➢ - type of local resources to be used and modalities for their use
   ➢ - type of materials or data to be exported/imported
   ➢ - benefit sharing measures, responsiveness to local research needs, procedures to facilitate effective
     capacity building
   ➢ - safety measures

➢ Documents to be reviewed:
   ➢ - copies of relevant Ethics Approvals from EU country host and non-EU country (Double Ethics Review)
   ➢ - if applicable: Material Transfer Agreement and copies of any authorisations, authorisation for export
     from EU, Insurance cover
Ethics issues: ENVIRONMENTAL PROTECTION AND SAFETY

- Applicable legislation:

- Possible ethical issues
  - Harm to the environment can occur as part of the experimental design of the research and as the result of undesirable side-effects of the technologies. If the research raises societal concerns about environmental or human health, societal engagement provisions should be incorporated in the Ethics Self-Assessment.

- Information to be reviewed: Details on health and safety measures to be implemented

- Documents to be reviewed:
  - safety classification of laboratory
  - if applicable: GMO authorisation and specific approvals
  - confirmation of compliance with national/local guidelines/legislation

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Ethics Issues: DUAL USE

➢ Applicable legislation:
   ➢ Council Regulation (EC) No 4286/2009 of 3 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items:
   ➢ Biological and Toxin Weapons Convention:

➢ Possible ethical issues:
   ➢ Trans-border transfers of dual-use materials, technologies and information
   ➢ Examples of dual-use research potentially affected by bans and standards in international non-proliferation laws: weapons of mass destruction related to dual-use research and the development of autonomous robotics, drones, and certain laser technologies

➢ Information to be reviewed:
   ➢ Explanations on the exclusive civilian focus of the research
   ➢ Details on:
     ➢ what goods and information used and produced in your research will need export licences
     ➢ how the research might affect current standards in military ethics

➢ Documents to be reviewed:
   ➢ confirmation that the inclusion of military partners and technologies relates to civilian applications
   ➢ if applicable: copies of relevant approvals from national export control authorities
   ➢ a detailed description on what risk mitigation strategies will be implemented to avoid negative implications on military ethics standards outlined in international humanitarian law

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Ethics Issues: MISUSE

- **Applicable legislation:**

- **Possible ethical issues:**
  - Potential misuse of materials, technologies and information:
    - A. Research that involves information on, or the use of, biological, chemical, radiological and nuclear security sensitive materials and explosives (CBRNE) and the means of their delivery
    - B. Research and the development of technologies that could have severe negative impacts on human rights standards (e.g. privacy, stigmatisation, discrimination) if misapplied
    - C. Research that has the potential for terrorist or criminal abuse

- **Information to be reviewed:** Details on
  - the legal requirements of the possession of such items
  - measures to prevent malevolent abuse
  - risk mitigation strategies

- **Documents to be reviewed:**
  - If applicable: copies of relevant approvals and personnel security clearances

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Ethics Requirements in Practice

- Each applicant is responsible for:
  - identifying any potential ethical issues
  - handling ethical aspects of their proposal
  - detailing how they plan to address them in sufficient detail already at the proposal stage.

- Which part of the proposal must be checked by the ethics reviewer?
  - Part A – ethics self-assessment
  - The entire proposal including Part B section 6, where the applicant provided a description of the ethics issues and related arrangements
Ethics Review in Practice

- **Ethics review process:**
  - **Pre-screening:** for proposals with no declared ethics issues, confirmation of "no ethics issues" is necessary = "ethics clearance".
  - If ethics issues are identified in the pre-screening by even one ethics reviewer only, a screening will follow.

- **Screening:** The reviewers must check all ethics issues and confirm that they are adequately addressed.

- **Assessment (RTD):** if serious or complex ethics issues require an in-depth analysis.
Ethics review in practice

Proposals without declared ethics issues → Pre-screening → Ethics clearance

Most of the proposals after pre-screening are expected to get an ethics clearance.

Proposals with declared ethics issues → Screening

Yes issue detected → Conditional ethics clearance

No issue detected

Please identify the issue and indicate the page number on which it can be found in the proposal.

Ethics clearance → Ethics assessment recommended → Ethics assessment run by DG RTD

Conditional ethics clearance

Please check and confirm that all ethics issues are adequately addressed.

Please provide the ethics requirements.

Only if serious or complex ethics issues require an in-depth analysis (exceptional case).
Ethics Report

The Ethics Report must contain one of the following opinion on the proposal:

1. Ethics clearance
2. Conditional ethics clearance
3. Ethics assessment recommended
Ethics Clearance

➢ Proposals are fully compatible with Article 34 of H2020 Grant Agreement:

➢ "The beneficiaries must carry out the action in compliance with:
  ➢ (a) ethical principles (including the highest standards of research integrity and
  ➢ including, in particular, avoiding fabrication, falsification, plagiarism or other
  ➢ research misconduct) and
  ➢ (b) applicable international, EU and national law.
  ➢ Funding will not be granted for activities carried out outside the EU if they are
    prohibited in all Member States.
  ➢ The beneficiaries must ensure that the activities under the action have an
    exclusive focus on civil applications."

➢ Only proposals that are 'ethics-ready' (i.e. respect ethical principles and
  applicable laws, provide the needed copies of Ethic Approvals, give clear
  information on the ethics issues ...) are granted ethics clearance by ethics
  expert.
Conditional Ethics Clearance

- Ethics assessment may result in a request for providing information before and/or after grant agreement signature
Ethics Assessment

- An Ethics Assessment is carried out by the Commission's DG for Research and Innovation on proposals raising serious ethics issues (e.g. severe interventions on humans), or on proposals whose ethics issues are particularly complex or perhaps even irreconcilable.

- An Ethics Assessment is automatically performed on all proposals that use hESC (human embryonic stem cells).

- In case of an Ethics Assessment recommendation, the ethics experts should list additional information and documents to be provided by the applicants prior to the Ethics Assessment in order to facilitate its conduct.
In which cases should ethics experts request Ethics Checks during the lifetime of the project?

- In case of **complex** and difficult ethics **issues**
- and if the **documents** provided are **not satisfactory**
- and if compliance with ethical review requirements need to be checked **during** the implementation of the project

- **Justification** of ethics checks is mandatory for ethics experts
- **Timing** should be proposed, indication of work package can be useful
Cross-cutting issues: Ethics and SSH

- Cross-cutting issues are fully integrated in the work programme (WP):
  - Social Sciences and Humanities (SSH) are integrated across all Horizon 2020 activities to successfully address European challenges
  - Gender dimension in the content of R&I - a question on the relevance of sex/gender analysis is included in proposal templates
  - The new strategic approach to international cooperation consists of a general opening of the WP and targeted activities across all relevant Horizon 2020 parts
    - The approach to providing 'automatic funding' to third country participants is restricted – see list of countries
    - You should check requests for 'exceptional funding'
  - Other cross-cutting issues such as science education, open access to scientific publications, ethics, standardisation, climate and sustainable development ... may also be included in the WP
  - You need to take into account cross-cutting issues if explicitly mentioned under the scope or expected impact of the call or topic
    - A successful proposal is expected to include the above elements, or convincingly explain why not relevant in a particular case
Horizon 2020 calls are aimed at solving complex societal problems and should therefore fund contributions from SSH disciplines that can tackle these problems. Contributions from SSH may appear alongside other disciplines.
**SSH-relevant Topic**

- In many topics, the ‘scope’ section indicates that there should be contribution from SSH. These topics have been ‘flagged’, and can be found on the Participant Portal (see list of SSH-relevant topics).

- Proposals under these topics are expected to take into account the **social, economic, behavioural, institutional, historical and/or cultural dimensions**, as appropriate, of a societal issue.
  - Even if proposals do not belong to an SSH-relevant topic, they may contain contributions from the SSH disciplines and should be evaluated as with other relevant aspects of the proposal.
  - Will be looked at for all 3 criteria.
How EU thinks about SSH

- EU research policy through Framework Programmes as its financial instruments, has had a significant effect for the establishment of the European Social Science and Humanities Area (SSHA) by contributing to changing how SSH do comparative research.
- From 3 SSH strands/themes of research to cross cutting approach
A brief history of SSH in Framework Programmes I

 ➢ Beginning with the 4th framework programme (1994-1998) large scale funding was allocated for social sciences

 ➢ The FP4-TSER- Specific programme of targeted socio-economic research, had only three strands/activities:
   ➢ Evaluation of science and technology policy options in Europe;
   ➢ Research on education and training; and
   ➢ Research into social integration and social exclusion in Europe
A brief history of SSH in Framework Programmes II

• In FP5 (1998-2002) the political choice was more ambitious and opened up the programme to a whole range of disciplines of social sciences.

• The budget for SSH increased, but was spread over many more disciplines and sub-disciplines in social sciences and some of the humanities.
Lowlights of SSH for the ERA policy process

- The prevailing view about SSH has been that social science systems produced fragmented research with researchers working within their national contexts.
- It was compartmentalized into disciplinary and sub-disciplinary boxes and lacked integration of knowledge necessary for relevant policy-making, especially at the European level.
- National SSH research communities were often unaware, partly due to language barriers, of research established in other countries.
Changes in how SSH do research

- Internationalization
- Inter-sectorial partnerships
- Social innovation and socio-technical integration
- Multi-inter-transdisiplinarity in EU research programme design and SSH
Permeability of disciplinary boundaries: SSH and STEM (Sciences, Technology, Engineering and Mathematics)

- **Multidisciplinarity** draws on knowledge from different disciplines but stays within their boundaries.
- **Interdisciplinarity** analyzes, synthesizes and harmonizes links between disciplines into a coordinated and coherent whole.
- **Trans-disciplinarity** integrates the natural, social and health sciences in a humanities context, and transcends their traditional boundaries.
Is transdisciplinarity a new discipline?

“Transdisciplinarity draws together theories and approaches to form a shared conceptual and analytical framework – a new discipline thus resolving in an integrated story”

http://www.net4society.eu/_media/PB_N4S_FINAL.pdf
The H2020 understanding of transdisciplinarity

“Trans-disciplinarity refers to approaches and methodologies that integrate as necessary (a) theories, concepts, knowledge, data, and techniques from two or more disciplines, and (b) non-academic and non-formalized knowledge”.

(Guidance for evaluators of Horizon 2020 proposals (Version 1.1 of 26 September 2014)
“Citizen Science”

“...refers to the general public engagement in scientific research activities when citizens actively contribute to science either with their intellectual effort or surrounding knowledge or with their tools and resources”.

A new ERA vision: Impact and Value for Money

- Moving away from disciplinary approaches to addressing Global Challenges
- Maximising the return to society from investment into science
Highlights and Lowlights for SSH

**Opportunities**
- SSH researchers have the core competences needed to address many themes related to the grand challenges.

**Risks**
- “Some lines of cultural and social research are at risk of being relegated into auxiliary disciplines and/or practices of technical expertise”. (AKA, 2012)
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THANK YOU