Ethics Reviews:

Experiences and (some) Advice

As. Prof. Efthimios TAMBOURIS

tambouris@uom.gr

Ethics Review Experience

- Involved in Ethics Reviews for the last 4 years

- Involved mainly in "remote" (meaning online, i.e. through Internet) reviews but also "central" (meaning in Brussels through physical meetings) reviews

- Reviewed proposals from many different areas and instruments, such as eHealth, Food-bio, ICT, People, European Research Council etc

- ICT academic background

- *Disclaimer: This presentation reflects personal experience and is not an official EU position, thus no "guarantee" is provided!*

Common Mistakes

1. Ethical issues are neglected altogether. Two cases:

   1. "Trivial" ethical issues are not identified

   2. Complex ethical issues are not identified

2. Ethical issues are acknowledged but are not handled properly in the Ethics section.

3. Ethical issues are acknowledged and handled properly in the Ethics section but nowhere else in the Description of Work (e.g. Work Packages, Project Management etc)

- "Handling" includes:

   1. Actual work on ethical issues

   2. Properly managing this work

(Some) Practical Advice

1. Determine whether your work (<u>or its impact</u>) involves ethical issues.

2. Get informed on relevant national and international ethical requirements, laws, regulations etc.

3. Prepare a plan to handle ethical issues.

4. Integrate this plan in your Description of Work.

5. If needed, properly manage work on ethical issues.

1. Identify possible Ethical Issues

- Support from EU:
    - See http://cordis.europa.eu/fp7/find-doc_en.html for:
        - Ethics check list
        - Supporting documents
    - See http://cordis.europa.eu/fp7/ethics_en.html#ethics_cl for "Ethics check list" on:
        - Informed Consent
        - Research on Human embryos/foetus
        - Privacy
        - Research on Animals
        - Research Involving Developing Countries
        - Dual Use

- *Common mistake: ethical issues are neglected all together, specifically in research areas where there is no relevant tradition e.g. ICT*

Ethics check list – 1

- Informed Consent

  – Does the proposal involve children?

  – Does the proposal involve patients or persons not able to give consent?

  – Does the proposal involve adult healthy volunteers?

  – Does the proposal involve Human Genetic Material?

  – Does the proposal involve Human biological samples?

  – Does the proposal involve Human data collection?

- Research on Human embryos/foetus

  – Does the proposal involve Human Embryos?

  – Does the proposal involve Human Foetal Tissue/Cells?

  – Does the proposal involve Human Embryonic Stem Cells?

- Privacy

  – Does the proposal involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?

  – Does the proposal involve tracking the location or observation of people?

Ethics check list – 2

- Research on Animals

  – Does the proposal involve research on animals?

  – Are those animals transgenic small laboratory animals?

  – Are those animals transgenic farm animals?

  – Are those animals cloning farm animals?

  – Are those animals non-human primates?

- Research Involving Developing Countries

  – Use of local resources (genetic, animal, plant, etc.)?

  – Benefit to local community (capacity building i.e. access to healthcare, education, etc.)

- Dual Use

  – Research having potential military/terrorist application

2. Get Informed on Relevant Requirements

- Get informed on relevant national, EU and international ethical requirements, laws, regulations etc.

- If developing countries are involved, compliance to EU standards is required.

- Support from EU:
  - See http://cordis.europa.eu/fp7/ethics_en.html for "Supporting documents"

- This should be reported in the Ethical Issues section of your proposal.

- *Common mistake: relevant requirements are not presented or are presented only at the EU level and not national*

3. Prepare a Plan

- Prepare a plan to handle ethical issues.

- The plan is obviously related to the nature of ethical issues involved

- Obtain permissions from local or national authorities, if needed and if possible before proposal.

- This should be outlined in the Ethical Issues section of your proposal.

- *Common mistake: Ethical issues are properly identified and relevant regulations are listed but there is no adequate evident that the consortium will handle them properly. In certain cases, it is evident that the consortium is very experienced in handling ethical issues in the past but did not properly documented the needed work.*

4. Integrate Plan in DoW

- Integrate this plan in your Description of Work.

- The relevant work should be clearly stated in the Work Packages etc.

- If permissions are needed, plan your time accordingly.

- This should be presented in the main body of the proposal (besides the Ethical section).

- *Common mistake: handling ethical issues is reported properly in the Ethical section of the proposal but is not evident whether and where this work would be carried out when someone reads Work Package descriptions.*

E. Tambouris, tambouris@uom.gr

5. Manage Ethical Issues

- If needed, manage properly work on ethical issues.

- This should be outlined in the Ethical Issues section but also integrated in your Description of Work (e.g. in description of Work Packages, Project Management etc).

- Decide whether you need to:

  - Manage Ethical Issues at the Task and/or Work Package

  - Have a Specific Task of Work Package on ethical issues

  - Have an (internal or external) ethics expert in the Steering Committee or Board

- *Common mistake: The proposal has properly identified and handled serious ethical issues but experts responsible for ethical issues are not high enough in the management hierarchy*

Summary

- In most cases, ethical issues can be easily handled by a consortium

- In some cases, it is evident that a consortium has the relevant expertise but has not devoted proper resources for the documentation

- This presentation aimed to present some guidelines for the most straightforward cases

- In certain cases however, ethical issues are not trivial and require much more attention; in this cases, advice from an ethics expert on this specific field might be needed

Thank you very much for your attention!!