ETHICAL BEST PRACTICE IN RESEARCH INVOLVING NON-EU COUNTRIES

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Agenda

- Key ethical issues for consideration
- Informed Consent
  - Competent adults
  - People with language and literacy difficulties
  - Children
- Data Management
- Research in low & lower-middle income countries
- Q & As

Key ethical issues

- Exploitation of research participants
- Exploitation of local resources
- Risks to participants, researchers, and staff of local co-operating organizations (NGOs, local charities, etc.)
- Research that is prohibited in the EU

Key points for consideration

- **Duty of Care**: acknowledging responsibility & facilitating supports, if necessary.
- Considering **political, social, and cultural context** → implications for the level of risk to participants/ researchers, and for consenting procedure (vulnerability, literacy etc.)
- Applying institutional/national/EU **ethical** and research **integrity** standards to non-EU jurisdictions
- Acting within the law of the land – awareness of relevant local legislation, competent authorities, required permissions etc.
- Liaising with local gatekeepers (NGOs, charities etc.)

Informed Consent - Adults

- Does the potential participant have the **capacity to consent** (legal & intellectual competence)?
- Written or Verbal? Can written consent be obtained? Written is always preferable
- Must be **voluntary** and **free from coercion**
- Must be **informed** (*information leaflet)*
- Must be **explicit**
- Must respect the **right to withdraw**
- Should agree terms for future use of data – *no blanket consent!*

Informed Consent - *Procedure*

- Typically involves providing information leaflet followed by signing of the consent form

- Information about the study should be given ahead of consenting to allow enough time to ask questions and make informed decision about participation

- Information should be presented in a **format** and **language** appropriate for the audience (no jargon/explain specific terms, plain language, clear and concise, easy to follow)

Participant Information Leaflet

UCD Human Research Ethics Committee (HREC) requires that the information leaflet addresses the following (as per **Q10** in the ***HREC Application Form***):

1. **Introductory Statement** (Researchers' names, affiliation, topic/title of the study)
2. **What** is this research about?
3. **Why** are you doing this research?
4. **How** will the data be used?
5. Why have they been **invited** to take part?
6. **What will happen** if they decide to take part in this research study?
7. How will you protect their **privacy**?
8. What are the **benefits** of taking part in this research study?
9. What are the **risks** of taking part in this research study?
10. Can they change their mind at any stage and **withdraw** from the study?
11. How will they **find out** what happens with this project?
12. Researchers' contact details (for additional queries)

Consent Form

Consent form should contain the following:

1. Participant's declaration of his/her rights and understanding of the information regarding participation and consent procedure.
2. Confirmation of participant's agreement to take part
3. Confirmation of participant's permission to use his/her data for a **specific** research purpose.

Consent Form - *guidelines*

- Avoid repeating information contained in the information leaflet
- Confirm the right to withdraw and clearly state its limits, if applicable
- If applicable, include options (tick boxes) for conditional consent, i.e. to be contacted in the future, for the use of data in future research/publications, for sharing of data with third parties etc.
- Should be signed by both the participant and the researcher
- Should be stored with the information leaflet (reference)

Consent Form – *example 1*

Participant's Consent including elements specific to the study

DECLARATION

I have read this information sheet and have had time to consider whether to take part in this study. I understand that my participation is voluntary (it is my free choice) and that I am free to withdraw from the research at any time without disadvantage. I agree to take part in this research.

I understand that, as part of this research project…….
I understand that my name will not be identified…..
I am voluntarily agreeing to....
I agree that the data can be used in the publication of higher degrees, scientific publications…
I agree that the de-identified data may be shared with **third parties**

Name of Participant (in block letters):

Signature:

Date: / /

Consent Form – *example 2*

Participants' Consent to participate <u>with conditions</u>

DECLARATION

I have read this information sheet and have had time to consider whether to take part in this study. I understand that my participation is voluntary (it is my free choice) and that I am free to withdraw from the research at any time without disadvantage.
Therefore, I agree to take part in this research (please tick the box) ☐

I hereby give permission for the use of the data collected from me using the following methods only: (please tick the relevant box or boxes you are agreeing to)

All data collected from me: ☐
De-identified data only: ☐
Personal Details only: ☐
Taped Interview (audio): ☐
Photographs: ☐
Film/Video/DVD: ☐

Name of Participant (in block letters):

Signature:
Date: / /

Consent - *People with language and literacy difficulties*

- Verbal/partially verbal consent or consent *by proxy* (not advisable)
- Facilitate **oral presentation** in a language-appropriate, clear and friendly manner (no quizzing, open-ended questions etc.)
- **Verbal consent process should be documented** (written summary of oral presentation of information leaflet etc. – step-by-step approach) and co-signed by a literate **witness** who must be present during oral presentation
- Participants should be given copies of a **written summary** of the oral presentation and consent form

Informed Consent -*Children*

- All children have the same right to consent as adults, including the ***right to dissent*** → ensure that they and others understand it
- **Information** should be comprehensive and appropriate to a child's age and evolving competencies → enable their full participating in the decision-making process
- Provide additional **guidance** to explain information, if necessary
- Use **innovative methods**, e.g. visual consent forms (photographs, story boards, illustrations, videos)
- **Parental/legal guardian consent** is usually necessary → consider **power dynamics** (community – parent – child) and limits of parental consent
- **Community leaders/representatives –** ascertain if they need to be consulted and give permission

Child's Consent – *challenges*

- **Competence**: are children capable of providing consent? (legal capacity, cognitive maturity)
- **Information**: How to ensure that children are fully informed?
- **Power imbalance**: how to ensure that consent is freely given? (risk of undue influence etc.)
- **Right to dissent**: how to minimize risks of children fearing exclusion, disapproval, or punishment, all of which can impact on their ability to dissent
- **Parental consent**: is it always required? (***role:*** protection and best interest assurance). Are there any limitation? What about abusive parents? Or research with unaccompanied or orphaned children?

ERIC Guidelines

Ethical Research Involving Children (ERIC) project

- The project aims to assist researchers and the research community to understand, plan and conduct ethical research involving children and young people in **any geographical, social, cultural or methodological context**.
- **ERIC Compendium** – available in four languages *(English, French, Spanish, & Korean)*
- Provides real life case studies

www.childethics.com

Human Subject Data – *nature and format*

- **Nature of data**: Is it personal? (human subjects), and is it sensitive? (health, sexual lifestyle, ethnicity, political views, religious or philosophical convictions),
- **Personal data format:** (1) anonymous; (2) de-identified (anonymized); (3) identifiable (identified); (4) potentially identifiable. See also Personal Data – Definitions & Examples
- **Data file format**: audio or video recordings, numerical, digital, paper-based etc.

Data Management - *continued*

- Key objective → to guarantee ***confidentiality***

- Establish clear **management protocols** for each stage of data life-cycle: collection, processing, analysis, storage, transfer, archiving/destruction

- Define and assign **roles and responsibilities** in relation to each of the stages

- Establish strict **data security** protocols: recording and storing devices (password protected and encrypted); security of IT servers, web cloud service, filing cabinets etc.

Transfer of Personal Data - *export*

Exporting data to non-EU jurisdictions

- Consult EC list of countries offering adequate data protection → **http://ec.europa.eu/justice/data-protection/international-transfers/adequacy/index_en.htm**
- If the country of destination is on the list → no additional requirements
- If not → enter into agreement with the recipient and obtain specific authorization from the national data protection agency

Transfer of Personal Data - *import*

Importing data collected in non-EU jurisdiction

- Check local regulations for permissions that may apply (relevant legislation, local authorities)
- Raw data should not be transferred without explicit consent of the participants – address this in the consenting procedure
- In absence of local regulations, apply EU regulatory standards and ethical best practice

Low & lower-middle income countries

From: **EC Guidance on How to complete your ethics self-assessment (H2020)**

- Could this research be carried out in an EU country?
- What benefit sharing measures will be taken?
- How does the project respond to local research needs?
- How will the project facilitate effective capacity building?
- How will the safety of participants, researchers, and staff be ensured?
  - Specific safety measures
  - Specific training for staff
  - Adequate insurance cover

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www.ucd.ie/researchethics/**policies_guidelines**

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http://libguides.ucd.ie/**data**