Scope of Ethical Review

Research project is subject to ethical review if it involves the use of one or more of the following:

- Human subjects
- Personal data (primary and secondary use)
- Human tissues and other biological material
- Animals

Objectives of Ethical Review

- To protect the rights of the participant
- To help minimise the risk which participant may be exposed to
- To promote best ethical practice in research
- To protect the researcher
- To protect institutional reputation
- To help improve quality of research

UCD Policies

UCD staff and students must comply with:

- **UCD Code of Good Practice in Research** – sets out standards of best practice in research for all researchers in UCD who are engaged in research with human or animal subjects

- **UCD Research Ethics Policy** - overview of research ethics in UCD and the requirements of the Research Ethics Committee and its sub-committees regarding the Research Ethics Approvals System

- **UCD Policy on the Use of Animals for Research & Teaching** - overview of the applicable statutory and UCD requirements

Key points for consideration - 1

- Who are the participants/informants?
- How will they be selected, recruited, consented?
- What will be asked of them?
- What kind of information will be collected
- By what means?
- What ethical issues/dilemmas and risks have been identified and how they will be dealt with
- How will the data be used and managed to ensure its **confidentiality**?

Key points for consideration - 2

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.)

Ethical best practice

Almost all projects which are subject to ethical review do carry **ethical issues** or **dilemma**. Therefore, researchers should:

1. **Acknowledge** the existence of ethical issues within projects
2. **Identify** ethical issues and dilemma specific to the project
3. **Address** these issues and describe how will you mitigate relevnat risks and by what means?

Common Ethical issues

- Obtaining informed consent
- Type and level of vulnerability
- Coercion
- Exploitation of research participants
- Risks to participants, researchers, and staff of local co-operating organizations *(NGOs, local charities, etc.)*
- Benefit-sharing

Informed Consent – *General Principles*

- Does the potential participant have the **capacity** and **competency** to consent?
- **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

OBJECTIVE: to provide potential participants with adequate information about the study in a language and format that is easy to understand and to follow and thus facilitate their decision-making process.

- **Introductory Statement** (Researchers' names, affiliation, topic/title of the study)
- **'What** is this research about?'
- **'Why** am I doing this research?'
- **'How** will your data be used?'
- 'Why have you been **invited** to take part?'
- **'What will happen** if you decide to take part in this research study?'
- 'How will your **privacy** be protected?'
- 'What are the **benefits** of taking part in this research study?'
- 'What are the **risks** of taking part in this research study?'
- 'Can you change your mind at any stage and **withdraw** from the study?'
- 'How will you **find out** what happens with this project?'
- Researchers' contact details (for additional queries)

Use the correct person throughout!

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 *and* future research/sharing with third parties (if applicable)

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 separate from raw data

Consent Form – *example*

Participants' Consent to participate with conditions

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 de-identified data collected from me for the following purpose: (please tick the relevant box or boxes you are agreeing to)

Publications and conference presentations: ☐
Future research (subject to ethical review): ☐
Sharing of data with third-parties for research purposes only: ☐

Name of Participant (in block letters):
Signature:
Date: / /

Name of researcher (in block letters):
Signature:
Date: / /

Vulnerability

Examples of vulnerable groups:

- Minors (children and adolescents >18yrs),
- Some elderly people*
- Minority groups vulnerable to discrimination (ethnic, sexual, gender)
- Migrants (**domestic & cross-borders**), refugees and asylum seekers
- Prisoners & persons incapacitated (e.g. under mental health law etc.)
- persons with certain physical or mental health and learning difficulties

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) – *legally not, but you should assume they* ***have competence to assent***

- **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?

Research with children – *Selected Guidelines*

- **ERIC** 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)*
- Guidelines and real life case studies

www.childethics.com

unicef

Office of Research-Innocenti

Working Paper: What We Know About Ethical Research Involving Children in Humanitarian Settings

- An overview of principles and literature
- Case studies
- UNICEF procedures relating to e.g. consent, confidentiality, payment and compensation, conflict of interest

www.unicef-irc.org

Vetting requirements

Ireland: Researchers who work with minors and certain vulnerable groups must be Garda-vetted as required by the law: *National Vetting Bureau (Children and Vulnerable Persons) Act 2012.*

Other jurisdictions: Always check local legal requirements to ensure that you are acting within the law of the land.

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, experiences of violence/discrimination)

- **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

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Read our leaflet