Research Ethics

What is it?

Conventions safeguarding the rights, dignity and welfare of people participating in research

How do we define Research which needs ethical approval?

- Research which 'uses' humans for the benefit of the researcher, the community or society, with little or no direct benefit to the individual subject, but with the possibility of harm, discomfort or inconvenience to that individual

That might mean:

- Medical intervention (by drug or procedure)
- Using tissue, either collected for the purpose or 'retained'
- Seeking confidential or sensitive information
- Raising issues which might disturb the subject
- Involving vulnerable or dependent research subjects

Principles of Ethical Research

- Autonomy
- Beneficence
- Non Maleficence
- Confidentiality

Essentials of Research Ethics

- Recruitment
- Assessment of risk
- Adequate precautions
- Informed consent
- Confidentiality
- Right to withdraw

Recruitment

- How are research subjects recruited?
- Is there any hidden compulsion or pressure?

- Are they classified as:
  - dependent?
  - vulnerable?
  - or in unequal relationship with researcher?

Risk Assessment

- **What are the hazards, dangers, discomforts or other form of disturbance to which the subject may be exposed? Are you, the researcher, at risk?**

  - Are you asking questions that might be disturbing to some people?
  - Are you placing them at risk of being disadvantaged?
  - Is the location safe?

What steps have been taken to minimise the risks and to cover possibility of an untoward event?

- Have you been honest with the participants about the risks?

- Have you provided contact numbers/addresses for an appropriate agency to provide help?

- Have you set up a lone worker protocol if you are working alone?

Confidentiality

How will you keep all information obtained confidential?

- **How will you store written data?**
- **How will you store electronic data?**
- **What is your policy on destroying primary data, such audio tapes?**

- **How will you deal with unexpected information which ought to be passed on in the interests of the volunteer?**

Informed Consent

Informed consent means:

- that the volunteer be aware of all the information needed to make a rational decision about participation
- That the volunteer should be asked for an unambiguous consent, preferably in writing, to participate

Informed Consent 2

The information sheet is crucial. It must:

- Be written in plain language, avoiding jargon and complicated medical concepts
- Tell volunteers who you are, why you are doing the research and what the objectives are
- Be clear about the procedures the volunteer will undergo, or the nature of questions to be asked

Informed Consent 3

- **Be clear about the risks and what measures are being taken to minimise these; and provide advice and back-up should the volunteer feel disturbed or unwell**
- **State the payment to be made**
- **State categorically that the volunteer may withdraw at any time without having to give a reason and without detriment to future treatment or services**

Informed Consent 4

The consent form must:

- Ask whether the subject has read carefully and understood the information sheet
- If any points of doubt have been explained to the satisfaction of the volunteer
- Ask the volunteer to consent to each aspect of the exercise. Consent must be positive. The assumption that a lack of response means consent is unacceptable

Informed Consent 5

- **Where children are involved, consent should be given both by the parent/carer and the child. In the case of a child, assent should be in a form appropriate to age or educational development**