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Valid Informed Consent for research

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Content

- The importance of consent;
- What is *informed* consent?;
- Participants that lack capacity;
- Studies involving children – assent and consent;
- The practicalities of consent;
- Good documentation;
- Questions and discussion.

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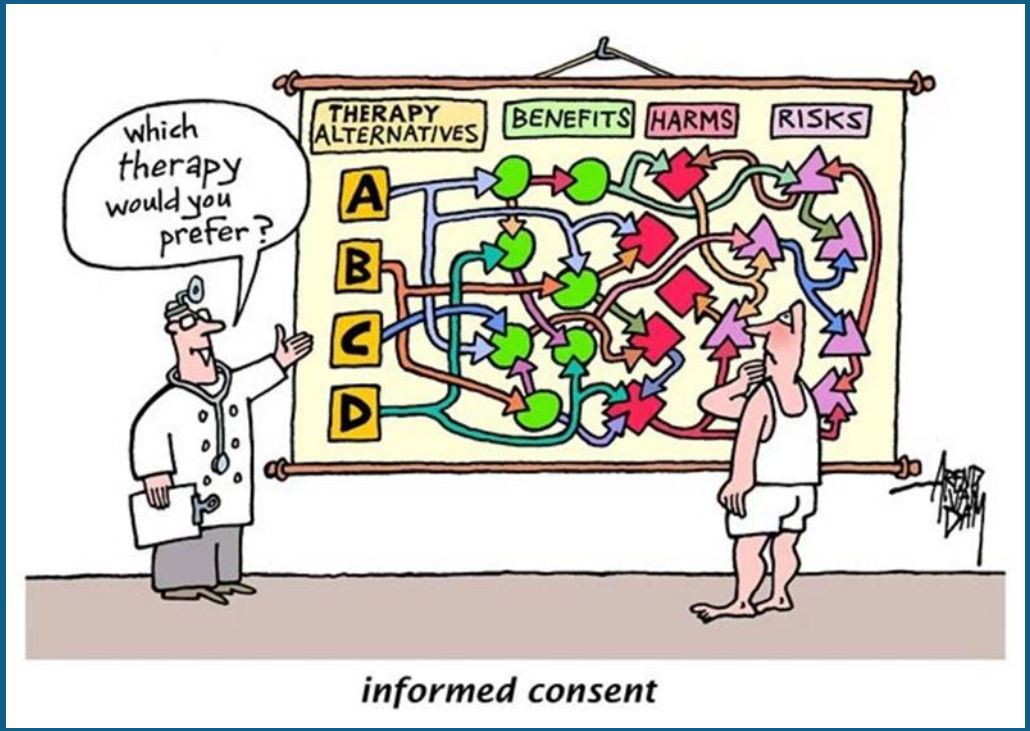
The importance of consent

- Learning from history;
- Improve protection of participants;
- Respect for participants;
- Encourage good science/practice;
- Ensure meticulous documentation;
- Improve quality of studies



informed consent

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The importance of consent – cont…

- The ***voluntary*** consent of the human subject is absolutely essential:
  - Person must have legal capacity to consent;
  - Should have “sufficient knowledge and comprehension” to make an “understanding and enlightened decision”;
  - Must be able to exercise “free power of choice” .

- Inform the subject of:
  - The nature, duration and purpose
  - The method and means
  - All inconveniences and hazards
  - Possible effects on health

There should be no force, fraud, deceit, duress, coercion.

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What is *informed* consent?

Informed consent is one of the founding principles of research ethics. Its intent is that human participants can enter research freely (voluntarily) with full information about what it means for them to take part, and that they give consent **before** they enter the research.

Consent should be obtained **before** the participant enters the research (prospectively). The minimum requirements for consent to be informed are that the participant understands what the research is and what they are consenting to.

There are two distinct stages to a standard consent process for competent adults:

- **Stage 1 (giving information)**: the person reflects on the information given; they are under no pressure to respond to the researcher immediately.

- **Stage 2 (obtaining consent):** the researcher reiterates the terms of the research, often as separate bullet points or clauses; the person agrees to each term (giving explicit consent) before agreeing to take part in the project as a whole. Consent has been obtained.

https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent

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What is *informed* consent – cont…

- Informed consent is a **process** and a basic human right;

- To give truly informed consent, potential participants need to understand the following:
  - The purpose of the research;
  - How long their participation will last;
  - Who is involved in the research;
  - The practicalities involved;
  - Benefits, risks and alternatives;
  - How data is managed and used;
  - For how long and where the data will be stored;
  - Purpose of the consent/agreement form;
  - Expectations if they agree to participate;
  - How information will be provided;
  - Participation is voluntary;
  - They may withdraw at any time;
  - Insurance and indemnity;
  - That the study (where applicable) has ethics approval.

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What is *informed* consent – summary

- Consent is a two step process and participants should be given at least 24hrs to consider the study/information;
- The information provided should be comprehensive, all areas are covered in BU's Participant Information Sheet template;
- Consent provides a reasonable assurance that the participant has not been deceived or coerced;
- The signature on the consent/agreement form alone is not evidence enough of the participant's informed consent;
- Before obtaining informed consent, the participant's capacity and understanding should be confirmed.

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Participants that lack capacity

The Mental Capacity Act (2005) states that “A person must be **assumed to have** capacity unless it is **established** that he lacks capacity”. Capacity must be assessed in terms of a person’s ability to **make a decision** at the point at which it is required.

Determining whether someone has the capacity to make a decision is a separate process to that of involving them in research. All potential participants should be assumed to have the capacity to make a decision unless proved otherwise, and should be given all practical support to make a decision for themselves wherever possible.

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Studies involving children and young people

- Under 16 year olds require *assent* and parental *consent;*
- 16 – 18 year olds, depending on the participant group and subject matter, may require assent and parental consent also;
- Specifically tailored Participant Information Sheets are required for children and young people - they should be age-appropriate in terms of language and pictures;
- For assent forms– see the ethics blog for examples and the Medical Research Council/Health Research Authority pages.

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The practicalities of consent

1. Read through each point with the participant and check their understanding – are you happy that they are fully informed?;
2. Witness the participant **initialling** the appropriate box (Section A) and boxes (Section B) as appropriate;
3. Once the appropriate boxes are complete, the participant should then write their name, date and sign the form;
4. The **Researcher** should then write their name, date and sign the form – **this is important and done at the same time**;
5. Provide the participant with a copy of the completed form;
6. File the original in the study file.

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The practicalities of consent – cont…

- Consider whether those responsible for obtaining informed consent are competent to do so, and are well supported in this role;
- Ensure that those obtaining informed consent are aware of the potential risks posed by the studies as well as the benefits;
- Ensure that those obtaining informed consent know the study and associated activities well enough to be able to answer any queries/address any concerns;
- The participant should not feel pressured, and remember that they can withdraw at any time* without having to give a reason.

*withdrawing their participation vs withdrawing data

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Good documentation and communication

- Study filing – keep all the consent/agreement forms filed securely;
- Ongoing consent, consent is a process - if there are multiple visits then verbal consent/agreement should be confirmed every time;
- Whenever new information arises, the participant should be provided with updates and ongoing consent confirmed. At times re-consent/gaining agreement again in writing may be appropriate;
- Amendments to study procedures/documents/dates should be submitted via the appropriate amendment process (online ethics checklist).

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Examples / Research Ethics Blog

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Questions and discussion

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