INFORMED CONSENT IN CLINICAL RESEARCH

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Informed Consent Definition

"A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form"

ICH GCP E6 (R2) Glossary

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Types of Consent for Research

Informed/Express/Explicit: Entails giving sufficient information about the research, without any form of coercion, so that prospective participants can make an informed and free decision about their involvement

Implicit/Implied: Not gained through formal methods, such as written or verbal approval. e.g. Return to questionnaire implying consent

Post-hoc: Consent that has, as the name implies, been sought and granted after the research has taken place

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Types of Consent for Research

Proxy: Should only be used when participants are unable to consent themselves or where it is legally necessary

Deferred/Delayed: Refers to the intent to obtain consent from either the patient or their representative at a later time, typically after research-related activities have commenced, for ongoing study participation (e.g. in emergency situation).

Assent: The agreement of someone not able to give legal consent to participate in the activity.

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Types of Consent for Research

Consent for future use (layered consent)

- Allows subject to decide if material or data can be used for future research
- Should present a choice of layered options e.g.
  - Material/data stored for future use **related** to current study **only if consent is obtained** at time of future research
  - Material/data stored for future use **related** to current study **without further consent** being sought
  - Material/data stored for future use **unrelated** to current study **only if consent is obtained** at time of future research
  - Material/data stored for future use **unrelated** to current study **without further consent** being sought

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General Data Protection Regulations (GDPR)

- Requires explicit **consent for processing data**
  - Consent must be ‘freely given, specific, informed and unambiguous’
  - should state specifically how the data will be processed, whether it will be transferred to a third party, provide notification that consent can be withdrawn at any time, and that if there are any changes in circumstances outlined (in information provided), data subject will be contacted prior to such change being implemented.
- PIL should inform patient about how data will be processed, how long retained etc.

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Ethical Principles

Autonomy (Respect for persons/Self determination):

- acknowledges a person's capacity to make personal choices & protects those who lack capacity
- Exercised in particular through the process of free and informed consent, which may be withdrawn without detriment at any time

Beneficence:/Non-maleficence

- maximising the potential benefits of the research and minimising the risks
- Includes scientific quality of study and expertise of researchers

Justice:

- the duty to neither neglect nor discriminate against individuals or groups who may benefit from research
- to avoid placing an unfair burden of research participation on particular groups - a principle known as **distributive justice**

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Ethics Committees

- Ethical approval of informed consent documents and processes
  - Process to be outlined fully in protocol and in ethics application
  - Documents to be approved include any material to be provided to patient - Patient information leaflets, information and instruction sheets, advertisements.
  - Any amendments to documents or processes must be approved before implementation
    - Only exception 'Immediate Hazard'
- Types of Ethics Committees?

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Why Patients Take Part in Research

Participating in research can have perceived benefits for pts:

- Access to experimental treatments that might give better outcomes than standard treatment
- Closer monitoring
- Increased access to members of team
- Extra investigations
- Altruism – genuinely want to help other people

Vital that patient is aware of experimental nature of research

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SCENARIO 1

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Conditions for Valid Informed Consent

- CAPACITY
- VOLUNTARISM
- DISCLOSURE
- COMPREHENSION

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Capacity

- Capacity for decision-making is defined as ‘the ability to understand, at the time the decision is being made, the nature and consequences of the decision in the context of the available choices’.
- A person lacks the capacity to make a decision if they are **unable**:
  - To understand the information relevant to the decision
  - To retain that information long enough to make a voluntary choice
  - To use or weigh that information as part of the process of making the decision, or
  - To communicate their decision

http://www.irishstatutebook.ie/eli/2015/act/64/enacted/en/pdf

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Consent in Emergency Situations

- If not possible to obtain consent from the prospective participant, consent of legally acceptable representative should be sought.
- If there is no representative present the individual can only be enrolled in research if the following criteria are met:
  - The research addresses the emergency needs of the individual involved;
  - The experimental interventions have a realistic probability of benefit equal to or greater than standard interventions;
  - The risks associated with the research are reasonable in view of the critical nature of the condition and the risks associated with standard interventions.
- Process of recruiting MUST have been described and received prior approval from a Research Ethics Committee

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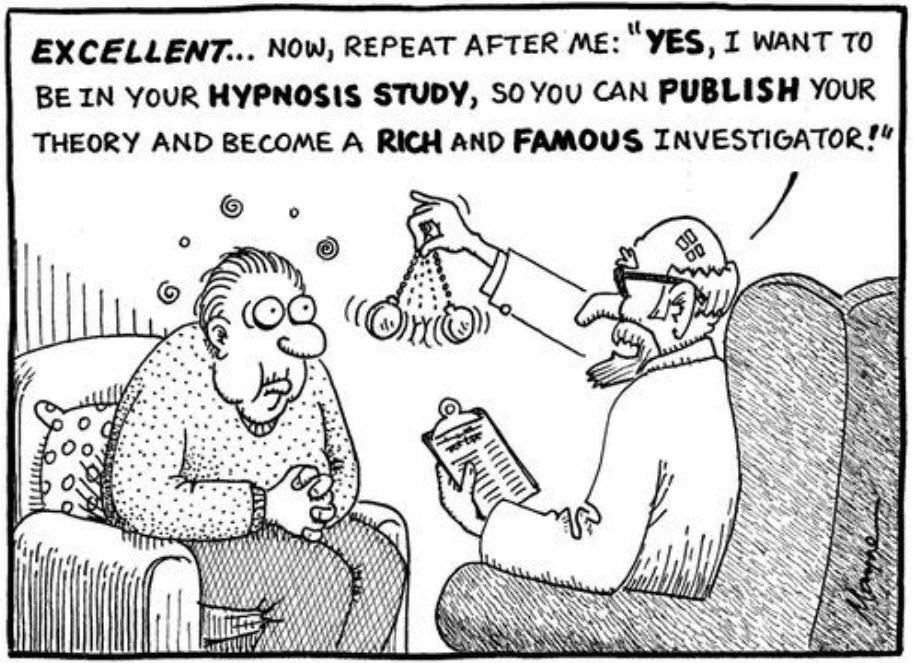
Who Can Seek Consent?



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Who Can Seek Consent?

- Should have sufficient knowledge about the research and be capable of answering questions from prospective of participants.
  - Knowledgeable about the research area
  - Appropriately trained in the protocol
  - Delegated to take consent by investigator
- In Ireland only a qualified physician or dentist may take consent for drug trials
  - Other team members may be involved in the consent process
- Each study should be individually assessed based on planned interventions and associated responsibility

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Who Can Give Consent?

The consent process and procedure for obtaining consent may occur with:

- an adult capable of providing consent
- the legally acceptable representative when the participant is an adult unable to give consent
- one or both biologic or adoptive parents when the participant is a child, or, in the absence of a parent, another person authorised under applicable law to consent on behalf of the child to participate in the research

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Consenting Procedure

- The informed consent ***document*** gives a summary of the clinical trial (its purpose, the treatment procedures & schedule, potential risks & benefits, alternatives to participation etc….)
  - Designed to begin the informed consent process with conversation between patient & research team
  - 2 elements: Patient Information Leaflet or Sheet & Informed Consent Form (ICF)
  - Usually combined but if treated as separate documents consent form must reference the version number and date of the PIL read and discussed
- The informed consent ***process*** provides ongoing explanations to the patient which will help the patient decide whether to begin or continue in the trial
  - Therefore, ***consent is an ongoing process***, rather than a one-time encounter

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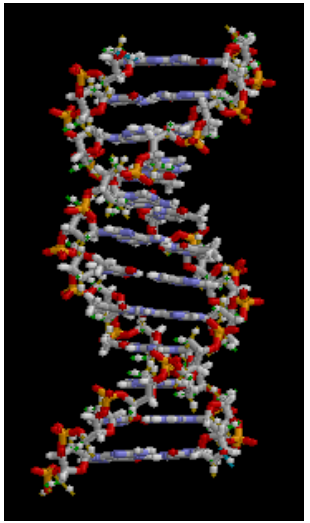
Genetic Research

- The Disability Act 2005 (part 4) states that consent for the processing of any genetic data to be derived from testing must be obtained
- Also stipulates that a person shall not process genetic data unless all reasonable steps have been taken to provide the data subject with all of the appropriate information concerning how the data will be used and any potential implications (For more information: HSE National Consent Policy)



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Key Points When Obtaining Informed Consent

- Avoid influencing a subjects decision to participate
- Patients legal rights to be protected
- Language used as non-technical as possible and understandable to the subject or representatives
- Disclosure of all pertinent aspects of the trial, including the written information approved by a REC
- All questions should be answered to the satisfaction of the subject
- Provide ample time and opportunity for making decision
- Consent form signed and personally dated before any study procedures

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Points to Remember!

Consent for research is more “thorough & expansive” than consent for treatment

- Patients may not distinguish between role of caregiver & researcher
  - Important for everyone involved in the consent process to realise their position of trust!
- Research is <u>always</u> optional
- Patient <u>always</u> has the right to change decision
- Patients who choose not to take part are not treated any differently in terms of care

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