

Informed Consent and Patient Involvement in Trials

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Overview

What is Research?

The Art of Science

Ethical Implications & Principles

Informed Consent

3 Example Studies

Patient Involvement

What is Research?

- Thomson (1976):
- *'Every art and every investigation and similarly every action and pursuit is considered to aim at some good!'*
- Research is about finding answers to questions we have or phenomena that we are unable to explain.
- Research means different things to different people

What is Research?

- To some people it may imply a large scale undertaking lasting many years with a full-time team and back-up resources.
- For others it might merely be looking a little deeper into something that interests or intrigues them on a personal level.
- Investigating into something unknown can lead to a very different and unexpected outcome.

The Art of Science

- Science is seen as a coherent body of thought about a topic over which there is a broad consensus among practitioners;
- Science is objective and therefore reliable;
- Social Research is concerned with theories, which challenge our understanding of the social world.

Ethical Implications

- Nuremberg codes of medical ethics were a result of criminal proceedings.
- The Nuremberg Codes were replaced by the Helsinki declaration, which was recently reviewed.
- The essential purpose of ethical research is to protect the welfare and the rights of research participants.
- One always has to ask if there is any other way of carrying out a certain project.

Ethical Principles

- Autonomy of all participants needs to be respected, this including voluntary and informed consent.
- Non-Maleficence means that the researcher should do no harm to participants.
- Beneficence implies that the research project needs to be of benefit, if not directly to the participants then more broadly to other researchers and society in general.

Ethics Committee

- Research Ethics Committees within the Health care system and other organisations have been set up to review research proposals and techniques.
- They may request changes in protocols and information sheet to protect any persons involved and ensure ethical adherence.

Informed Consent

- Why is this project being done?
- Why have I been chosen?
- Do I have to take part?
- What will happen to me if I take part?
- What are the possible benefits of taking part?
- Will my taking part in this project be kept confidential?
- What are the possible risks and disadvantages of taking part?
- Who has reviewed the project?

Consent Form

- A legal document referring to the information sheet to ensure the safety of participants and study investigators;
- To confirm taking part and ensure voluntary withdrawal without consequences;
- To only carry out procedures stated in the information sheet;
- To protect investigator from claims related to stated procedures;

The Process of Research



- Idea or Phenomena
- Literature Review
- Design
- Methodology
- Method
- Samples
- Analysis
- Outcome

Reasons to participate in Trials

- Financial reasons
- Access to new yet unlicensed treatments
- Altruism
- If it doesn't harm me, I don't mind?
- Guilt
- Regular medical monitoring
- General Research interest

Example 1

Discordant Couple Study

A diagram consisting of a thin black curved line that starts on the left side of the frame and curves downwards and to the right. The curve ends in a dark gray shaded area that is roughly triangular in shape, pointing towards the bottom right. The text 'Discordant Couple Study' is written in a black, sans-serif font across the middle of the curve.

Discordant Couple Study: A study to investigate how some people are protected from HIV infection

Within a relationship has the HIV-negative partner been exposed to the virus at some time and remained HIV negative?

Rationale

- Investigation of couples with clear sexual histories where safe and unsafe sex with regular and casual partners is identified and ongoing.

Viral, culture, sequencing

Immunology

CTL/CD4 responses

Discordant Couple Study

Recruitment of monogamous couples provides several advantages:

Isolation of virus from peripheral blood and genital sites will enable quantification and characterization of donor strain.

HIV-resistant immune responses from the partner can be clearly defined against the specific strain of virus.

Example 2

Should we treat HIV
Seroconversion?



Treatment of Primary HIV Infection

- Preservation of immune function
- Surrogate markers and ? improved prognosis
- Reduction of transmission risk
- Acceptability, tolerability and potency
- Baseline resistance

Example 3

- How do Health Care Professional understand 'risk' in relation to sexual behaviour among HIV positive gay men?

Aims of the Project

- To consider HCP's understanding of sexual behaviour of HIV positive gay men;
- To detect possible themes in HCP's understanding of particular types of sexual behaviour of HIV positive gay men;

Patient Involvement

- Sharing experiences;
- Presenting the patient's view;
- Offering ongoing feedback meetings;
- Equal and balanced relationship as patient contributes actively;
- Active involvement in trials enables direction and focus of new treatment options;
- Closer follow-up care enables closer relationship with clinician;

Information

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Declaration of Helsinki

<http://www.bioscience.org/guides/declhels.htm>