

Start	End	Topic	Speakers
16:30	16:35	Introduction	William Gibson
16:35	16:45	History of Research Ethics	William Gibson
16:45	17:00	Current Frameworks - Declaration of Helsinki	Diane Newman
17:00	17:10	Special Populations and Industry	Jean-Jacques Wyndaele
17:10	17:30	Project 1 for discussion	William Gibson Jean-Jacques Wyndaele Diane Newman
17:30	17:50	Project 2 for discussion	William Gibson Jean-Jacques Wyndaele Diane Newman
17:50	18:00	Discussion	William Gibson Jean-Jacques Wyndaele Diane Newman

Description

Background

Research ethics are central to the conduct of clinical research; a clear understanding of the underlying principles of ethical research is crucial both to ensure the dignity, safety, and welfare of participants, but also to all valid, high quality research to be published and disseminated. Unethical research harms us all; the participants, the researcher, and the wider scientific and clinical community.

This workshop, presented by experts from the ICS Ethics Committee, will provide participants with a solid understanding of the history of research ethics and the current legal, ethical, and moral considerations they need to consider if planning their own clinical research, or participating in projects through recruitment or data collection.

Key Learning Points

The workshop aims to give those colleagues who are not used to planning research projects, submitting ethics applications, or participating in research through, for example, recruitment or data collection, a solid grounding in the knowledge and principles required to conduct themselves and their research in an ethical manner and in accordance with local, national, and international guidelines and laws, allowing them to produce high-quality, publishable research.

Take Home Messages

- The History of Research Ethics (Nuremburg, Declaration of Helsinki, Tuskegee)
- The development of Research Ethics Guidelines and their current application
- How local differences may apply
- The importance of special groups, such as children or older adults
- How to incorporate these principles into your research

The Workshop

The first phase of the workshop shall be more didactic, during which participants will be given a background of research ethics, with a discussion of the history of the field, including the development of the Nuremburg Code and Declaration of Helsinki, and an outline of current guidelines. This will focus on those which are internationally agreed, with discussion of the regional differences when relevant. In particular, the Declaration of Helsinki and the CHI's Good Clinical Practice guidelines shall be presented.

Following this, there will be a discussion of special populations, including children, older adults, and those with physical or intellectual impairment, and how these groups require special protection. The particular challenges of research involving sensitive topics, such as incontinence, sexual dysfunction, and pelvic floor health, shall be emphasised. The challenges of dealing with Industry sponsored research and the particular ethical issues this can raise will be discussed.

The majority of the time for the workshop shall comprise a series of fictitious research projects, presented to the participants as if they were being presented to the Health Research Ethics Board. Participants will be invited to comment on the research proposals, identifying areas of the application which are good, well described, and in accordance with the guidelines previously presented, and which aspects may be problematic or need changing. The facilitators will encourage discussion among the attendees to explore the issues, and will ensure that a diversity of viewpoints and backgrounds can contribute. If possible, online voting such as Slido, shall be used to gauge the feeling in the room and spark discussion of contentious points.

Take Home Messages

Research ethics are crucial for the safe conduct of clinical research, and a solid understanding of the legal, moral, and ethical frameworks for conducting research is imperative for anyone involved in research, from the PI to clinic staff identifying potential participants.

Aims of Workshop

Participants in clinical research give their time and can put themselves at risk to answer questions, allowing us to answer questions and improve care. This act of altruism is reliant on the research being conducted in an ethical manner.

Using interactive examples of problematic research projects, this workshop, presented by the ICS Ethics Committee, will give participants of all backgrounds an overview of the principles of research ethics, and the tools to ensure that their research complies with internationally-accepted ethical guidelines, including Good Clinical Practice and the Declaration of Helsinki.

Educational Objectives

The workshop shall comprise three parts;

An introduction to the history of research ethics, including the Tuskegee Experiment, the Nuremburg Code, and the Declaration of Helsinki

A discussion of current research ethics guidelines, such as the ICH's Good Clinical Practice, with focus on those guidelines which are internationally agreed, and the differences found in different countries.

A series of fictitious research ethics applications will be presented by the panel for discussion by the attendees. These applications will have deliberate ethical issues to be identified, such as coercion, undue incentives, high risk, and confidentiality breaches. This section will be interactive, with the attendees invited to identify the ethical problems and suggest solutions, acting in the place of a Health Research Ethics Board (HREB)

The workshop will be pitched at clinicians of all disciplines who are involved in the design and conduct of clinical research, and who may be involved in the process of gaining HREB approval for their projects, and will give attendees an appreciation of the process of HREB review and practical points to how to successfully apply for ethics approval.

Learning Objectives

1. Understand core ethical principles in research, including informed consent, beneficence, and justice.
2. Identify and address ethical issues in research design, data collection, and interpretation.
3. Apply ethical frameworks to real-world scenarios and navigate ethical dilemmas in their own research practices.

Target Audience

Urology, Urogynaecology and Female & Functional Urology, Bowel Dysfunction, Conservative Management

Advanced/Basic

Intermediate

Suggested Learning before Workshop Attendance

<https://www.ich.org/page/efficacy-guidelines#6-2>