Chapter 7.4 Getting ethical approval for your research

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Further reading

1. Council for International Organizations of Medical Sciences and WHO. International ethical guidelines for biomedical research involving human subjects. Geneva, Switzerland: CIOMS. 2002 https://cioms.ch/shop/product/international-ethical-guidelines-for-biomedical-research-involvinghuman-subjects-2 (accessed 22 February 2022).

Summary of this document: Biomedical research often involves the use of human subjects, but researchers must comply with relevant national and international guidelines.

In this guidance document, the CIOMS and WHO offer ethical guidelines to countries seeking to define their national human subjects research policies. It details universal ethical principles, ethical review mechanisms, informed consent, and working with vulnerable populations. This guidance contains information targeted towards low- and middle-income countries that may be partners in international research projects. The authors conclude that while ethical conflicts are bound to occur in biomedical research, clear guidelines can help researchers to avoid and resolve these moral issues. Readers seeking current ethical guidance should note that this guidance has been superseded by the CIOMS' 2016 *International ethical guidelines for health-related humans involving humans*.

2. Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2). Swiss. ICH. 2016. https://www.ich.org/fileadmin/Public_Web.../E6/E6_R2__Step_4_2016_1109.pdf.

Summary of this document: Good clinical practice (GCP) encourages the ethical conduct and reporting of human subject research.

In this guidance document, the ICH establishes a unified GCP standard for the European Union, Japan, and the United States. It seeks to improve the regulatory acceptance of clinical data across these countries. This addendum also addresses recent advances in clinical research, including the use of centralized monitoring and electronic tools. The guidance document outlines sponsor and investigator responsibilities, in addition to monitoring and reporting obligations.

3. Panel on research ethics. The Tri-Council Policy Statement 2: Course on Research Ethics. Ottawa, Canada: Government of Canada. [Online tutorial] https://tcps2core.ca/welcome (accessed 22 February 2022).

Summary of this document: This online resource can familiarize researchers with the *Tri-Council Policy Statement* (TCPS), a joint policy on human research ethics issued by Canadian federal research agencies.

In this online training course, the Panel on Research Ethics introduces the 2nd edition of the TCPS. It introduces research ethics to human subject investigators of all fields with no specific emphasis on discipline or methodology. This training resource constitutes mandatory institutional training for researchers in Canada. It contains eight learning modules and a user glossary.

4. Policy on research involving human participants. London, United Kingdom: Wellcome Trust https://wellcome.ac.uk/funding/guidance/wellcome-trustpolicy-position-research-involving-human-participants (accessed 22 February 2022).

Summary of this document: Many funding agencies have stringent policies for funded projects involving human subjects. Familiarity with these policies is important for ensuring compliance.

In this guidance webpage, the Wellcome Trust outlines its human subject research policy. It defines human subject research, researcher expectations, and participant rights and interests. It then requires researchers to comply with legal obligations, with an emphasis on confidentiality, approval, and consent. The guidance concludes with a series of best practice guidance for researcher consideration. The Wellcome Trust emphasizes that while human subject research is valuable, all funded researchers must abide by both the Wellcome Trust's standards and relevant government frameworks.

5. World Medical Association Declaration of Helsinki - Ethical principles for medical research involving human subjects. Ferney-Voltaire, France: World Medical Association. 2013 https://www.wma.net/policies-post/wmadeclaration-of-helsinki-ethical-principles-for-medical-research-involvinghuman-subjects (accessed 22 February 2022).

Summary of this document: The Declaration of Helsinki is a key set of ethical principles on human subject research to which all researchers are morally bound.

In this document, the World Medical Association outlines how researchers must respect the rights of subjects when conducting research. It argues that all subjects have self-determination and the capacity to make informed decisions and that subject safety should be a researcher's priority. It also highlights the need for special sensitivity when researching vulnerable subjects. The document emphasizes that the ethical principles of the Declaration of Helsinki supersede any conflicting legislation or professional interests.