Human Subjects Regulations [1]

Human Subject Research

Human subject research (HSR) is research involving individuals about whom an investigator obtains data through intervention or interaction with the individual, or identifiable private information.

Several requirements must be met if your research involves human subjects. You must start fulfilling the requirements as early as possible to avoid delays in research start-up.

Training

Key Personnel must complete training on human subject protections. Key Personnel includes anyone involved in the consent process, research procedures, or data collection. Key personnel can also include anyone who accesses private identifiable information for research purposes. It also includes researchers from the location where the research will be conducted if you are not going to obtain local IRB approval. Check your institution's requirements before you prepare your submission.

The NIH maintains a compendium of information [8] about requirements for HSR in many countries. Partner institutions also have requirements that must be met so you should discuss the requirements with collaborators in advance to ensure proposed research is approvable by each collaborating institution.

Contact risk management at your campus early to initiate a quote for Clinical Research Insurance.

IRB Approval

You must submit your HSR to your campus institutional review board (IRB). The review process can take time so complete this submission as soon as possible. If your research involves more than one UC campus, consider registering your project in the IRB Reliance Registry [9]. This registration will allow collaborating UC campuses to use one UC IRB to review the research, reducing the burden of multiple submissions.

Next, check your institution's requirements for international research. In many cases, this research will need to be approved by an IRB in the location where the research will be conducted (local IRB). This approval is in addition to your institution's IRB approval.

Last updated: 6 Dec 2016

Planning International Human Subjects Research

When planning international human subjects research, remember to gather the following materials for IRB submission:

Initial protocol application

You must include the Initial protocol application and associated documents (e.g., surveys, questionnaires, study information). The application must list all international locations involved in the study, and the research plan must indicate that this is an international protocol. All foreign investigators collaborating in the research study must be listed on the IRB application. Include any aliases or alternate spellings and affiliation information.

Informed Consent Documents

Informed consent document(s) in English. Informed consent documents should be translated into the local language after IRB approval. Translated documents should state who performed the translation services.

Local Approval

Investigators must comply with both U.S. regulations and local policies and regulations governing the international research sites. All studies must have evidence of local approval by an IRB, Ethics Board, or Independent Ethics Committee (IEC) familiar with the local research context and local law, or a letter explaining why such a review is not possible. If no local ethics approval is in place, at a minimum, there must be endorsement of the project by the local authority/institution involved in the research. No research can begin until local approval has been obtained and submitted to the UC IRB. It is important to do your homework early and, if possible, enlist a local collaborator to help you address the site's requirements to obtain local ethics reviews and permissions to conduct research at that international site.

Planning Ahead

- Establishing Legal Presence Abroad [10]
- Hiring Abroad [11]
- Medical Liability Insurance [12]
- UCOP Office of Risk Services Foreign Liability Insurance [13]
- Medical Students Providing Patient Care [14]

Last updated: 30 Nov 2016

International Ethical Standards and Procedures for Research with Human Subjects

Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

The Declaration of Helsinki (DoH) [15] is widely regarded as the cornerstone document on human subject research. It provides medical researchers a guide the ethical conduct of research involving human participants and specifically addresses protections for study participants with regard to the risks, burdens, and benefits of participating in studies as well as participants' rights to privacy, confidentiality, and informed consent. The DoH was developed by the World Medical Association [16] (WMA). The WMA is an international organization of over 95 medical associations and has published a number of guidelines and reports that address standards in medical education, ethics, and science.

ICH Guideline for Good Clinical Practice

The International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice [17] (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

International Ethical Guidelines for Health-related Research Involving Human Subjects

The International Ethical Guidelines for Health-related Research Involving Humans [18], sometimes informally referred to as CIOMS Guidelines, is a set of ethical principles regarding human experimentation created in 1993 by the Council for International Organizations of Medical Sciences [19] (CIOMS) and updated in 2016. CIOMS is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949.

Ethical Consideration in Biomedical HIV Prevention Trials

Updated in 2012, the Ethical Consideration in Biomedical HIV Prevention Trials [20] offers guidance on ethical considerations in HIV prevention research based on extensive consultation and lessons learned in biomedical HIV prevention research. Although the guidelines specifically address trials of biomedical HIV preventive interventions, they are also relevant to trials of behavioral HIV prevention methods.

Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries: Report and Recommendations of the National Bioethics Advisory Commission

The Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries: Report and Recommendations of the National Bioethics Advisory Commission [21] discusses ethical issues associated with international research subject to U.S. regulations in developing countries, where local technical skills and other key resources for protecting human participants are scarce.

Universal Declaration on Bioethics and Human Rights

The Universal Declaration of Bioethics and Human Rights [22], adopted by the United Nations Educational, Scientific, and Cultural Organization [23] (UNESCO) in October 2005, addresses ethical issues related to medicine, life sciences,

and associated technologies as applied to human beings. The aim of the declaration is to provide a universal framework of principles and procedures to guide states when they formulate policies in the field of bioethics, as well as to recognize the importance of scientific research and the benefits derived from scientific and technological development.

Fogarty International Center Bioethics Information and Resources

The Fogarty International Center Bioethics Information and Resources [24], part of the NIH, supports basic, clinical and applied research and training for U.S. and foreign investigators working in the developing world. Since its formation, Fogarty has served as a bridge between NIH and the greater global health community to facilitate exchanges among investigators, provide training opportunities, and support promising research initiatives in developing countries.

Presidential Commission for the Study of Bioethical Issues

The Presidential Commission for the Study of Bioethical Issues [25], created by Executive Order 13521 on November 24, 2009, is an advisory panel to the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission oversaw a thorough review of current regulations and international standards to assess whether they adequately protect human participants in federally funded research. The Commission offers 14 recommendations to improve the current system, as provided in its report entitled Moral Science: Protecting Participants in Human Subjects Research [26].

World Health Organization (WHO)

The WHO's Ethics and Health Initiative [27] examines a range of bioethical issues—such as access to health services, organ transplantation, and research with humans—raised by WHO's own activities.

Office of Human Research Protections

Office for Human Research Protections (OHRP) International Compilation of Human Research Standards [28]. The OHRP International Program works to ensure that human subjects outside of the United States who participate in research projects conducted or funded by HHS receive an equal level of protection as research participants inside the United States. This site contains a compilation of over 1,000 laws, regulations, and guidelines on human subjects protection in over 100 countries.

Last updated: 27 Sep 2017

Responsible Conduct of Research

Responsible conduct of research (RCR) is defined as the practice of scientific investigation with integrity. It involves the

awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

All undergraduates, graduate students, and postdoctoral researchers supported by the National Science Foundation (NSF) must complete mandatory RCR training. Additionally, researchers supported by certain NIH programs, including training grants, are also required to complete RCR training. RCR training helps researchers learn how to address the ethical issues that inevitably arise in research. An RCR course typically covers the following areas: ethics, conflict of interest, responsible authorship, policies for handling misconduct, data management, data sharing, and policies regarding the use of human and animal subjects.

Each campus offers an RCR program. Please contact your respective Research Compliance office for information about the RCR program at your campus.

RCR Resources

- ORI Introduction to Responsible Conduct of Research [29]
- Online Research Ethics Course [30]
- Doing Global Science [31]

Last updated: 8 Aug 2016

Additional Guidance

Visit the following resources to learn more about Human Subjects Research.

International Compilation of Human Research Standards

The International Compilation of Human Research Standards [32] contains more than 1,000 laws, regulations, and guidelines on human subject protections in 130 countries, as well as standards issued by a number of international and regional organizations.

Data Security

Information stored on your laptop can be at great risk for theft or corruption, or confiscation by authorities. Encryption software is contraband when crossing some borders. If you are encrypting patient information, be sure your software will not alarm border patrol. This may be in direct contrast to your human studies requirements. Visit Data Security [33] to learn more.

Clinical Trials

The US government requires that clinical trials be registered on ClinicalTrials.gov [34].

Field Ethics

Research ethics have a human and a scientific component. They are complex, and you may need advice when you are in remote areas. Work with your CHR and develop a resource for accessing that ethical perspective when you are

abroad.

Last updated: 2 Nov 2017

Campus IRB Directory

UC Berkeley

Human Research Protection Program [35]

UC Davis

Office of Research [36]

UC Irvine

Human Research Protections [37]

UC Los Angeles

Office of the Human Research Protection Program [38]

UC Merced

Research Compliance and Integrity [39]

UC Riverside

Office of Research Integrity [40]

UC San Diego

Human Research Protections Program [41]

UC San Francisco

Human Research Protection Program [42]

UC Santa Barbara

Office of Research [43]

UC Santa Cruz

Office of Research [44]

Lawrence Berkeley National Laboratory

Human and Animal Regulatory Committees Office [45]

Last updated: 9 Dec 2016

Last updated: 8 Aug 2016

Links
[1] https://www.ucgo.org/human-subject-regulations
[2] #qt-view__vertical_tab_section__block_22
[3] #qt-view__vertical_tab_section__block_22
[4] #qt-view__vertical_tab_section__block_22
[5] #qt-view__vertical_tab_section__block_22
[6] #qt-view__vertical_tab_section__block_22
[7] #qt-view__vertical_tab_section__block_22
[8] https://clinregs.niaid.nih.gov/index.php
[9] https://irbreliance.ucop.edu/
[10] https://www.ucgo.org/establishing-legal-status-abroad
[11] https://www.ucgo.org/hiring-abroad
[12] https://www.ucgo.org/insurance-liability
[13] http://www.ucop.edu/risk-services/risk-financing-claims/foreign-liability.html
[14] http://www.aamc.org/download/181690/data/guidelinesforstudentsprovidingpatientcare.pdf
[15] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
[16] http://www.wma.net/e/
[17] http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf
[18] https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
[19] http://www.cioms.ch/
[20] http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf
[21] http://bioethics.georgetown.edu/nbac/clinical/Vol1.pdf
[22] http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/
[23] https://en.unesco.org/
[24] http://www.fic.nih.gov/ResearchTopics/Pages/Bioethics.aspx
[25] http://bioethics.gov/
[26] http://bioethics.gov/cms/sites/default/files/Moral%20Science%20June%202012.pdf
[27] http://www.who.int/ethics/en/
[28] http://www.hhs.gov/ohrp/international/index.html
[29] http://ori.hhs.gov/education/products/RCRintro/index.html
[30] http://ori.hhs.gov/education/products/montana_round1/research_ethics.html
[31] http://www.interacademycouncil.net/File.aspx?id=29431
[32] http://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html
[33] https://www.ucgo.org/technology-security
[34] http://clinicaltrials.gov/
[35] http://cphs.berkeley.edu/
[36] http://research.ucdavis.edu/
[37] http://www.research.uci.edu/compliance/human-research-protections/index.html
[38] http://ora.research.ucla.edu/ohrpp/Pages/OHRPPHome.aspx
[39] http://rci.ucmerced.edu/irb
[40] http://research.ucr.edu/ORI.aspx
[41] https://irb.ucsd.edu/
[42] http://irb.ucsf.edu/
[43] http://www.research.ucsb.edu/compliance/human-subjects/
[44] https://irb.ucsc.edu/
[45] https://commons.lbl.gov/display/harc/Home