CHAPMAN UNIVERSITY | INSTITUTIONAL REVIEW BOARD

International Research

Purpose

1) Chapman faculty, staff or students conducting research outside of the United States (US) or with participants outside the US must respect domestic regulation, university policy and applicable foreign requirements for protecting human participants. All international research must adhere to recognized ethics codes such as the Declaration of Helsinki, the Nuremberg Code, and/or the Belmont Report.

Policy

1) Chapman researchers must obtain Chapman University IRB approval prior to commencing research activities internationally.

2) Research must be conducted in compliance with local laws, policies and regulations (e.g., privacy laws that affect data recording and storage practices). Some countries may require obtaining an equivalent of an IRB approval in their country. It is the PI's responsibility to be familiar with all of the relevant requirements and abide by them. Some helpful resources for this purpose include:

    a) If working in collaboration with a local investigator, rely on the collaborator's expertise

    b) If working in collaboration with a local investigator who is affiliated with a local university or research institution, seek an ethics approval from that institution (in addition to Chapman IRB approval)

    c) Researchers may be required to obtain approval from a foreign research ethics board. Check the International Compilation of Human Research Standards for information about laws related to research-relevant activities in over 100 countries.

    d) Where local regulations do not exist, an expert in the culture of the other country should be consulted about the appropriate agency, if there is one, that would typically provide a level of approval.

3) Where there are two or more sets of standards for the conduct of research, the research must meet the higher standard of protection for human subjects. For example, if a foreign country does not require signed informed consent from participants, the Chapman IRB would expect a meaningful consent process to take place whereby the study is explained to individuals, and they be allowed to choose whether or not to participate.

4) All researchers (Chapman and others) are expected to comply with US regulations and guidelines and any applicable regulations of the country in which the research is performed. See specific examples below.

5) Researchers are reminded to talk to the Export Control Officer when conducting research outside the US.

Last revised: 09May2023
Version superseded: 14Sep2022

Additional Considerations

1. Investigators are encouraged to contact the IRB to discuss issues related to international research. Researchers should have knowledge about the cultural, political, or socioeconomic differences that may bear on the conduct and purpose of the proposed research, including issues related to privacy.

2. IRB submissions should include a consent form and recruitment materials in the local language and in English.

3. If the researcher does not speak the language of the country in which the research will be conducted, they must describe how communication with participants will take place (e.g., via a local interpreter) throughout the research and not only during recruitment and when obtaining consent.

Resources for International Research

a) For federally funded studies, researchers must ensure that the international site(s) have an active Federal Wide Assurance ("FWA") with the Office of Human Research Protections (OHRP) if they will be engaged in non-exempt human subject research. Researchers may search this public database to determine if the international site has an active FWA.

b) OHRP also provides a listing of Social and Behavioral Research Standard researchers should consider reviewing when proposing research in foreign countries.

c) The Council for International Organizations of Medical Sciences (CIOMS) provides a manual entitled International Ethical Guidelines for Biomedical Research Involving Human Subjects which should be considered by investigators conducting biomedical research outside the US.

d) The World Health Organization (WHO) publication "Ethical and safety recommendations for intervention research on violence against women" provides researchers with best practice for conducting survey research on violence against women.

e) When research is being conducted in the European Union (EU) or if participants are citizens of the EU, the General Data Protection Regulations (GDPR) apply. Chapman researchers must provide participants with an additional consent form specific to GDPR which can be found on the IRB website.

Revision history:

May 2023 - Clarified that there must be a means to communicate with non-English speakers throughout the research and not only at the time of recruitment and consenting

14Sep2022 - original publication date

Last revised: 09May2023
Version superseded: 14Sep2022