International Research

Purpose

The purpose is to outline the policy and procedures for International research.

Definition

General Data Protection Regulation (GDPR) is a European law which establishes data protections for privacy and security of personal data about individuals located in or transferred from the European Union and European Economic Area (EEA), regardless of the citizenship status of the individuals.

International Research is research which is proposed to take place outside of the United States. It may involve activities which take place on foreign soil, which access foreign human subjects remotely (e.g., Internet), or which access data about human subjects from the foreign location.

Policy

International activities present several challenges in the review of research involving human subjects (participants). Review boards are required to have and document knowledge of the "local research context" and may require additional information from investigators before final approval of foreign site protocols may be granted. Local research context involves knowledge about socio-economic, political and cultural factors that influence every part of the research realm. Researchers must be aware that foreign cultures may have diverse authority structures. These structures may greatly influence the consent process and the identification and reduction of potential undue influence or coercion.

When engaging in international research, investigators must consider local laws and customs, local IRBs, agencies or "gatekeeper" organizations, and informed consent alternatives. To aid researchers with this task, the Office of Human Research Protections (OHRP) has published its ***International Compilation of Human Research Standards.*** This compilation lists the over 1000 laws, regulations,

and guidelines that govern research involving human subjects in hundreds of countries, as well as standards from a number of international and regional organizations. Its purpose is to help ethical boards, investigators, advisors and others involved in international research to familiarize themselves with the laws, regulations, and guidelines where the research will be conducted, and to assure these standards are followed appropriately. OHRP has also published two documents concerning Social and Behavioral Research: (1) ***International Social/Behavioral Research Standards – Description*** and (2) ***International Social/Behavioral Research Standards – Analysis***. Since these compilations change annually, links may be found on the IRB's Regulations webpage.

European Union and European Economic Area (EEA)

Research involving the collection, use and transfer of personal data (i.e. directly or indirectly identifiable) of those located in the EEA, regardless of their citizenship, must also adhere to the General Data Protection Regulation (GDPR). Please refer to the GDPR policy.

Requirements

All investigators proposing to conduct research internationally must complete the Collaborative Institutional Training Initiative's (CITI) international module as part of their human research course training.

Investigators must also:

- Provide a statement asserting that he/she has reviewed *The International Compilation of Human Research Standards* and/or the *International Social/Behavioral Research Standards*' - (1) *Description* and (2) *Analysis* for the country involved and adheres to the respective location's laws, regulations or guidelines that govern research involving human subjects
- Provide detailed information about where the study will be conducted (geographic location, performance site, etc.)
- Provide information about the current social, economic and political conditions

- Provide information about whether there are any additional risks that subjects might face as a result of participation
- Consider the most appropriate method for obtaining informed consent, taking into account the literacy level of the subjects, confidentiality concerns and cultural climate
- For non-English speaking participants, review and adhere to the IRB's translation policy (refer to the policy on Non-English Speaking Participants)
- Submit a copy of the local IRB, ERB or equivalent ethics committee approval, where possible

Additional elements are required in the application and informed consent form for research involving the collection, use or transfer of personal data of subjects who are located in the European Union (EU) or European Economic Area. Please refer to the GDPR policy.

Procedures

1. If not completed initially, all investigators and research assistants complete the international module as part of the required human research course training via CITI.
2. With an IRB or ERC submission, the investigator includes a statement about having reviewed the Office of Human Research Protections' International Compilation of Human Research Standards, and/or its Social/Behavioral Standards and adheres to what is described for the specific country. If the country's standards require additional information, the PI provides it.
3. The investigator addresses other requirements about the location and its conditions, any additional risks for this population, the appropriate method of obtaining informed consent, the language being used, and any foreign IRB or equivalent approvals.
4. If subjects are located in the EU or EEA, the investigator includes required information from the GDPR in the application and informed consent form.

Related Policies

- General Data Protection Regulation
- Non-English Speaking Participants

History

11/02/2017 – Updated OHRP's International Compilation for 2018; provided a definition and adjusted formatting

05/25/2018 – Updated with OHRP's Social/Behavioral standards and EU requirements; added procedures

07/24/2018 – Updated links to the current International Compilation.

07/15/2019 – Updated for addition of GDPR information