UMSL | Research
University of Missouri–St. Louis

Institutional Review Board (IRB)

Guidelines for Protections for International and Non-English Speaking Participants

1. Introduction

Federal Regulations require the selection of subjects to be equitable. In ensuring this requirement, the IRB takes into account the purpose and the setting in which the research will be conducted.

The purpose of this guidance is to aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the additional protections of vulnerable populations.

2. International Participants

UMSL IRB policies do not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research.

For federally sponsored or supported research, where procedures differ from the DHHS regulations, department or agency heads may determine the procedures prescribed by the institution afford protections that are at least equivalent to those provided in DHHS policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements in DHHS policy. See 45 CFR 46.101 (g-i) for additional information.

Researchers should have sufficient knowledge of the local customs and traditions to carry out the research in a way that protects the rights and welfare of the participants while producing viable research results.

OHRP provides a compilation of regulations and guidelines that govern human subject's research in other countries, as well as standards from a number of international and regional organizations. [See OHRP International Compilation of Human Subject Protections at https://www.hhs.gov/ohrp/sites/default/files/2018-International-Compilation-of-Human-Research-Standards.pdf

Researcher Responsibilities:
When studies are conducted in other countries researchers should be knowledgeable about the local laws and customs, which apply to the research, and the cultural context in which they will be working.

The researcher should consider influencing factors including, but not limited to:

- Local Laws
- Regulations
- Customs
- Socio-economic factors
- Politics
- Culture
- Language
- Literacy

These factors may affect the study design, the risks, and the consent process.

Potential Risks:

Some items to consider:

1. Methods may have increased risk when being conducted in a different country;
2. Innocuous questions may be offensive;
3. Maintaining or assuring confidentiality may be difficult; and
4. Breach of confidentiality may be dangerous for subjects.

Obtaining Informed Consent:

Informed consent is a decision to participate in research, by a competent individual who has received the necessary information; who adequately understands the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation. In some circumstances, it may be inappropriate to document consent by using the standard written and signed consent document. The consent should be obtained in the language that is most familiar to the prospective participant.

Other factors to consider are the potential for different rules on determining who may serve as a legally authorized representative, age of majority, children as subjects and potential differences in the authority structure.

IRB Review: The IRB will review in accordance to the regulations that apply to the local area. The most stringent requirements for protection of human subjects will prevail when there are differences. The IRB office will ensure appropriate expertise and knowledge of the country(ies) either through IRB membership or consultants. The IRB will also confirm the qualifications of the researchers for conducting research in that country(ies).

Federally Funded/ FDA regulated Research

1. For federally funded research, the regulations of that sponsoring agency apply and the required federal protections must be provided. It is not sufficient to provide "equivalent" protections.
2. FDA and ICH-GCP regulations apply to international research studies utilizing drugs, devices or biologics
http://www.fda.gov/RegulatoryInformation/Guidances/ucm122049.htm

3. For DHHS funded research, 45 CFR 46 applies. For other guidance by OHRP on international research, see https://www.hhs.gov/ohrp/international/

European Union General Data Protection Regulations (GDPR)

The European Union's GDPR regulates the processing (e.g. use, access, collection, recording, storage, or transmission) of all **personal data** about individuals in the European Economic Area (EEA)-based operations and certain non-EEA organizations that process personal data of individuals in the EEA, regardless of citizenship or residency status of the individual to whom the data pertains. It applies to the processing of personal information:

1. Through activities within the borders of EEA countries;
2. That is related to offering goods and services to EEA residents; or
3. That involves monitoring the behavior of EEA residents.

The following countries making up the EEA are adopting the GDPR: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lichtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and UK.

Personal Data is any information that relates to an identified or identifiable living individual. Different pieces of information, which collected together can lead to the identification of a particular person, constitute personal data.

Examples of personal data include, but are not limited to
1. A name and surname
2. A home address;
3. An email address;
4. Income and banking information;
5. An identification card number;
6. An Internet Protocol (IP) address;
7. A cookie ID;
8. Electronic location data;
9. Phone identifiers; or
10. Data held by a hospital or doctor which could uniquely identify a person.

Activities Subject to the GDPR
1. Activities involving the processing (i.e. collection) of personal data is being collected from one or more research participants physically located in the EEA at the time of data collection (even if the participant is NOT an EEA resident).
2. Activities involving the transfer of personal data collected under the GDPR from an EEA country to a non-EEA country.

Requirements for Data Collection and Access
The researcher is required to collect, in a transparent manner, only the minimum necessary information for the defined research purpose. When the personal data of an EU subject is collected, used, or accessed, the researcher must present certain information to the subject noted below.

Consent Process
1. Consent records, including time and date of consent, must be maintained for each subject. In the case of verbal, online, or any other type of undocumented consent, the Principal Investigator is responsible for maintaining a consent log indicating each subject (either by name or study ID number) and the date and time that they provided consent.
2. Consent must be explicit. If the consent form or consent script serves multiple purposes (e.g., a consent form that is also the recruitment email), then the request for consent must be clearly distinguishable within the document. Furthermore, when processing is conducted for more than one purpose, consent must be obtained for each purpose.
3. Each subject has a right to withdraw consent, at any time. Each subject must be informed of this right prior to giving consent. Withdrawal of consent must be as easy as giving consent.
4. Consent must be an affirmative action. This means that opt-out procedures or prechecked boxes indicating consent are not permitted.
5. Consent information must be provided in clear and plain language in an intelligible and easily accessible format. Consent forms using excessive jargon or that do not have separate sections with section headings will be returned for revision.
6. Consent must be freely-given. Individuals in a position of authority cannot obtain consent, nor can consent be coerced. This means that faculty members or teachers cannot obtain consent from their own students.

<u>Consent forms must contain the following information:</u>

- The identity of the Principal Investigator;
- The purpose of data collection;
- The types of data collected, including listing of special categories:
    - Racial or ethnic origin;
    - Political opinions;
    - Religious or philosophical beliefs;
    - Trade union membership;
    - Processing of genetic data;
    - Biometric data for the purposes of unique identification;
    - Health data; and/or
    - Sex life or sexual orientation information;
- The right to withdraw from the research and the mechanism for withdrawal;

- Who will have access to the data;
- Information regarding automated processing of data for decision making about the individual, including profiling;
- Information regarding data security, including storage and transfer of data;
- How long data will be stored (this can be indefinite);
- Whether and under what conditions data may be used for future research, either related or unrelated to the purpose of the current study.

Rights of Research Subjects / Data Storage

The data of individuals from the European Union must be stored in a way that enables the following rights:

1. The right to access the data, free of charge, in an accessible, comprehensible format.
2. The right to object to a particular use of that data.
3. The right to correct the data, without undue delay, in the event the individual feels that it is incorrect, incomplete, or inaccurate.
4. The right to "be forgotten," or to erase all data relating back to that person in an irreversible fashion. Parents of children and children each individually hold this right, so either of those parties can require a child's data to be deleted.
5. The right to move data; this means that the individual can ask you to transfer it to them, or to another party, in a commonly-used and machine-readable format.

The GDPR permits the retention of personal data for only as long as necessary to achieve the specific purpose for which it was collected. It must be deleted after that time. If a subject requests their previously collected data be erased, contact the IRB immediately to ensure the data has been appropriately erased.

Data Breach

If there is a data breach which could pose any risk to participants, participants must be informed of the breach without undue delay. Data breaches must be reported to the UM Office of General Counsel within 24 hours. An Event Report also has to be submitted within 5 business days to the IRB.

Coded Data vs Anonymized Data

For data to no longer considered personal data, it must be rendered anonymous in such a way that the individual is not identifiable. The anonymization must be irreversible. If a link or key exists between the data and subject identifiers (Pseudonymized data/coded data), the data is not anonymous. It is considered personal data, regardless of whether the investigator has access to the key. This is in stark contrast to US regulations protecting human subjects.

Data from Children

The GDPR defines a child (for the purposes of using or accessing personal data) as an individual under the age of 16. Parental consent is required for any personal data

collected regarding a child under the age of 16. NOTE – individual member states may utilize a lower age of consent (no lower than 13 years) within their own jurisdiction.

Investigators conducting research with data from the EU must comply with the responsibilities established by the GDPR. Failure to comply with these regulations results in non-compliance, monetary fines, and reputational harm.
See the EU GDPR website for more information: https://eugdpr.org/

3. Non-English Speaking Participants

When enrolling non-English speaking research subjects, investigators must have a plan to manage communications with the participant during ***all phases*** of study participation. This extends beyond recruitment, the consent process and initial enrollment, to include study visits as well as possible unexpected phone calls or follow-up questions. It is the investigator's responsibility to be fully prepared to communicate with all participants during any phase of the study.

Submitting Translated Materials
When investigators enroll non-English speaking subjects or subjects with limited English proficiency and materials distributed to those subjects in their native language (non-English), the IRB requires that both an English version and the non-English versions of materials be submitted to the IRB for review. The IRB also requires that the non-English version be "back-translated" by someone other than the original translator.

Materials may include, but are not limited to:

- Questionnaires
- Recruitment Materials (Flyers, Newspaper Ads, Brochures, etc.)
- Consent Documents & HIPAA Authorization Form

In most cases, it is in the best interest of the investigator to submit translated versions of materials after the English versions receive IRB approval (in case modifications are required by the IRB). If waiting to submit translations, at initial submission the protocol should note that translated versions will be submitted once English versions are approved. Translated versions can be submitted before the IRB issues full approval or via an Amendment form after the IRB issues full approval. The translated documents must be approved by the IRB *before* they are used in the study.

4. References:

21 CFR 50.27(b)(2)
45 CFR 46.117(b)(2)
OHRP "Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English"
FDA Information Sheets "A Guide to Informed Consent"
AAHRPP, Inc. Elements II.3.F, II.4.A