**University of Idaho**

**Institutional Review Board**

**Changes to Consent for Research Conducted Outside of the United States**

If you plan to conduct research outside of the United States, please follow the instructions below:

1. Determine the country or countries in which you plan to conduct research. List them to be included with your protocol.

2. Check for regulatory requirements [here](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html). The IRB Coordinator can assist you with interpreting these. You should also have familiarity with the foreign countries and local permission to conduct research.

3. If a foreign language is primary, plan to include translated documents of the Consent, Recruitment, and other materials with your IRB protocol. This only needs to be done in the final stage after the IRB has approved these documents.

4. If you plan to use local persons as interpreters or research assistants, the Primary Investigator may have them take the IRB required human subjects’ training or can document other training. This should be addressed in the IRB protocol.

5. The consent document needs to address all of the factors listed above. If you will specifically be conducting research in the European Economic Union, the European Economic Area, certain other countries, or worldwide, there are additional requirements under the General Data Protection Regulations that must be followed. These include:

* Collection of sensitive data (racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic/genomic data, biometric data, health data, sexual beliefs, and sexual orientation) all require specific mention in the consent form and the subject must explicitly agree to its collection in writing.
* The identity of the persons/entities collecting, transferring, and storing this data must be mentioned.
* The purpose of collecting the data must be stated.
* The subject must be informed of their right to withdraw consent. There must be a stated process on how to withdraw consent as easily as it was to give consent. The subject must be told that withdrawal of consent does not apply to data that was already collected.
* Information on whether the data will be transferred to another country and whether that country has similar privacy laws.
* Explicit consent must be obtained to conduct secondary analysis of any sensitive data used for a new purpose; broad consent for secondary research is not allowed.
* Explanation of when the data will be de-identified and when it will be destroyed.
* Explanation of how and where the data will be stored.

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