

IRB Policy 39: Transnational Human Subjects Research

Date: February 7, 2011, revised May 4, 2011, revised February 9, 2015

I. Pertinent Definitions:

Transnational Research: Research conducted outside of the United States of America.

For VA research:

VA international research is defined as any VA-approved research conducted at international sites (i.e., not within the United States (U.S.), its territories, or Commonwealths), any VA-approved research using either identifiable or de-identified human biological specimens or identifiable or de-identified human data originating from international sites, or any VA-approved research that entails sending such specimens or data out of the U.S. This definition applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including MOUs, CRADAs, grants, contracts, or other agreements. Research conducted at U.S. military bases, ships, or embassies is not considered international research.

International research includes multi-site trials involving non-US sites where VA is the study sponsor, a VA investigator is the overall study-wide PI, VA holds the IND, or the VA manages the data collection and the data analyses. International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator (i.e., the PI for the study as a whole is not a VA investigator). Sending specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA investigator on sabbatical at an international site) is considered international research. Remote use of data that is maintained on VA computers within the United States or Puerto Rico and accessed via a secure connection is not considered international research.

II. Summary Policy

Federal regulations require the organization to ensure that research performed in other countries meets equivalent levels of protection that would be required in the Organization's principal location, taking into account local laws and cultural context. When research is sponsored by a U.S. federal agency, the regulations of that agency apply.

III. Special Requirements

Prior to approval of transnational research, the IRB will:

1. Ensure that appropriate expertise and knowledge of the country either through IRB membership or consultants is obtained.
2. Confirm the qualifications of the Researchers and Research Staff for conducting research in that country
3. Seek knowledge of local laws
4. Consider if post-approval monitoring will be required, and if so, the appropriate level and timing for the monitoring.
5. Address Consent process and other language issues to ensure that the consent process is appropriate
6. Communicate and coordinate with local IRBs or ECs when appropriate.
7. Ensure that all policies and procedures that are applied to research conducted domestically will be applied to research conducted in other countries, as appropriate.

In addition, for VA studies:

1. All international research must also be approved explicitly in a document signed by the VA medical facility Director, except for Cooperative Studies Program activities which must be approved by the CRADO.
2. The research should be relevant to VA's mission and the care of Veterans, or is directly relevant to VA's role as a health care provider in a period of local or national emergency, or supports the mission of another Federal agency (e.g. DoD or NIH) through an interagency agreement or similar mechanism
3. There should be adequate protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel.
4. There should be appropriate security of VA data and VA sensitive information and storage of data and specimens in accordance with all applicable VA requirements.
5. The investigators should comply with the applicable VA policies related to the identification and resolution of conflicts of interest of research personnel.
6. All data should be obtained in accordance with international ethics rules and regulations pertaining to human research subjects and consistent with FR Vol. 70, No. 57, pp15322-15327, March 25, 2005 "Protection of Human Subjects, Proposed Criteria for Determinations of Equivalent Protections". .
7. All international sites should hold an international Federal Wide Assurance (FWA).
8. The research should be approved by the IRB or Research Ethics Board of the participating site(s) that are listed on the international FWA.

IV. Responsibilities

The Principal Investigator (PI) must complete the xform section Supplemental form for Transnational research.

- For initial review using the expedited procedure, and modifications and continuing reviews where the determinations relevant to transnational determinations made on the previous review have changed, the assigned reviewer completes the Transnational Reviewer section of the xform to document determinations required by policy and submits with other review documents.
- For initial review using the convened IRB, and for modifications and continuing reviews where the determinations relevant to transnational determinations made on the previous review have changed, the assigned reviewer completes the Transnational Reviewer section of the xform and the convened IRB documents in the minutes the determinations required by policy.

Complaints, non-compliance and upirtsos in transnational research are handled according to relevant IRB policies. If the complaint, non-compliance or UPIRTSO review require appropriate expertise and knowledge of the country that is not available through IRB membership, an external consultant will be utilized to obtain that expertise/knowledge.