

Department: UAMS Institutional Review Board
Policy Number: 2.8
Section: Relationships
Effective Date: July 31, 2002
Revision Date: July 23, 2004; January 24, 2011; March 11, 2011, February 15, 2016;
July 17, 2020; September 15, 2023

SUBJECT: International Research

Policy:

All transnational Human Subject Research submitted to the UAMS IRB shall be reviewed according to the policies and procedures that are applied to Human Subject Research conducted domestically. These policies will apply throughout the project, including initial and continuing review and any modifications. When such research is sponsored by a U.S. federal agency, the regulations of that agency apply.

Research with a transnational component may also be subject to other institutional requirements, such as import/export control review.

Procedure

A. Investigators shall ensure:

1. Submissions provide complete descriptions of all research activities, including those done overseas or those involving non-US sites. The role of the UAMS workforce members and/or UAMS agents in transnational research must be fully described. The submission is to specifically address:
 - a. Researchers and staff conducting research outside the U.S. are qualified to conduct research there and sufficiently versed in local laws and cultural context
 - b. Any post-approval monitoring plans address the transnational aspect of the research
 - c. Procedures to be put into place to address any subject complaints, non-compliance, or unanticipated problems involving risks to subjects or others.
 - d. Any other institutional requirements pertaining to transnational research, such as import/export control review and completion of any necessary forms related to the disclosure of foreign relationships/activities, are met.

B. IRB Review considerations specific to transnational research.

1. The IRB may invite consultants as described under IRB Policy 3.9 to participate in the submission's prereview or review to ensure the transnational site's local context considerations are adequately addressed.
2. The IRB may consider the oversight of a local ethics board or equivalent group adequate to ensure local context requirements are addressed.
3. A local ethics board may have additional requirements. The PI must ensure the requirements of both any local review board and the UAMS IRB are met.

REFERENCE

AAHRPP Element I-3