Institutional Review Board

Knowledge of the Local Research Context Policy

Scope

Applies to Mayo Clinic Human Research Protection Program personnel when involved in Human Subjects Research for which the Mayo Clinic Institutional Review Board (IRB) is the IRB of Record.

Purpose

To describe the responsibilities of the Mayo Clinic IRB and investigators to obtain and demonstrate knowledge of the laws, regulations, and customs where research is to be conducted - the 'local research context'.

Policy

Mayo Clinic IRB obtains sufficient knowledge of the local research context, regardless of the geographical location of the research, in order to fulfill its responsibilities to the protection of human research subjects under its Federalwide Assurance (FWA).

Investigator Responsibilities

- The investigator must provide documentation of the local research context such as:
  - Types of subject populations to be involved
  - Geographical area in which the research will be conducted, and/or
  - Other relevant factors that may influence the conduct of the proposed research.
- As required by the IRB, the investigator must provide documentation to adequately address the qualifications of the investigator(s) and study staff to conduct research in a location, and to demonstrate knowledge of local laws, regulations, customs, and practices.
- The investigator must promptly report any changes in the local research context to the IRB.

IRB Responsibilities

The IRB will have the experience and expertise necessary to review and make determinations regarding the local research context. This may be achieved through:

- IRB member personal familiarity of the local research context
- A written review by a consultant(s) with knowledge of the local research context
- A consultant may be invited to participate in the convened meeting discussion of the research proposal.
- The IRB will review and confirm that the researchers are qualified to conduct research in the local context and are knowledgeable of local laws, regulations, customs, and practices. The IRB will seek the advice of legal counsel, as necessary.

International Research

All policies and procedures that are applied to research conducted domestically are applicable to research conducted in other countries. The Mayo Clinic IRB, through its policies and procedures, will ensure the safe and ethical conduct of international research, including communication and coordination with the IRB of the host country. Refer to the IRB document, "International Research" for detailed requirements.

Policy Notes

N/A

Related Procedures

N/A

Related Documents

International Research

Definitions

N/A

References

OHRP Resource: International Compilation of Human Research Standards

Owner

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Contact

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