International Research Policy

Scope

Applies to personnel at the Mayo Clinic Human Research Protection Program (HRPP) and research when Mayo Clinic Institutional Review Board (IRB) is the IRB of Record for human subject research conducted outside of the United States (U.S).

Purpose

To outline requirements and responsibilities pertaining to human subject research performed outside of the U.S. and under the purview of the Mayo Clinic's HRPP and/or its IRB.

Policy

- A Mayo Clinic investigator, or an investigator at an institution for which the Mayo Clinic IRB is the IRB of record, must have IRB approval to conduct non-exempt human subjects research anywhere in the world. Human subjects research performed outside of the U.S. must meet the same level of protection of human subjects as required domestically. The research must take into account the laws, culture, and customs of the international institution/site (see IRB document titled Knowledge of the Local Research Context and Office for Human Research Protections [OHRP] document "International Compilation of Human Research Protections"). Approval by the non-U.S. institution/site (local) IRB (or equivalent) is also required.
- All applicable Mayo Clinic IRB policies and procedures that are applied to research conducted domestically will be applied to research conducted in other countries. Researchers are required to perform the research activities as reviewed and approved by the Mayo Clinic IRB and the local site IRB.
- When research is conducted or supported by a U.S. federal agency, the requirements and regulations of that agency apply. In addition, approval to conduct U.S. federally funded research at non-U.S. institutions or sites requires that the site hold a Federalwide Assurance (FWA) with OHRP and that local IRB approval is obtained.
- When the research is not conducted or supported by a U.S. federal agency, the non-U.S. site need not hold an FWA, however, the local IRB must be registered with the U.S. Department of Health and Human Services (DHHS) OHRP. Registration is the responsibility of the local IRB.
- For research conducted outside the U.S. where the Mayo Clinic investigator does not travel to the international research site, portions of this policy must be applied as relevant. E.g. completion of international training, obtaining local ethics board approval and/or letter of agreement to conduct the research, translating consent forms and other subject contact materials, detailing consent processes in the Mayo IRB application, documenting investigator qualifications to conduct research at the outside location.

When Mayo Clinic collects data from subjects who are in the European Economic Area (EA), the European Union (EU) General Data Protection Regulation (GDPR) may apply. Refer to Mayo Clinic's General Data Protection Regulation Compliance Policy.

Investigator Responsibilities

- Before submitting the study to the Mayo Clinic IRB, the Principal Investigator (PI) and study staff listed in the IRB application must complete training in the conduct of human subjects research in an international setting and upload a certificate(s) of completion, or completion report(s) in the electronic IRB (IRBe) application under "Supporting Documents".
    - Mayo Clinic investigators and study staff are required to successfully complete the online Collaborative Institutional Training Initiative (CITI) "International Research" module.
    - The online CITI "International Research" module is recommended for relying organizations for which the Mayo IRB is the IRB of Record; however, relying organizations may select alternate, but equivalent programs.
    - In addition to the CITI training course, the Mayo Clinic Integrity and Compliance Office requires that Mayo Clinic investigators and study staff involved in any capacity in the conduct of international research complete training pertaining to the Foreign Corrupt Practices Act (FCPA). This training must be completed before the initiation of any and all international research activities. The Mayo Clinic investigator and applicable study staff will be sent a link to the training via email by the Integrity and Compliance Office.
- The PI is responsible for communication and coordination with the local IRB for the non-U.S. institution/site.
- If the research is conducted or supported by a U.S. federal agency, the PI will obtain documentation of a FWA for the non-U.S. institution/site and include this documentation in the "Supporting Documents" section of the Mayo Clinic IRB application.
- If the research is not conducted or supported by a U.S. federal agency, the PI must obtain documentation of the local IRB's registration with the U.S. DHHS OHRP and include this documentation in the "Supporting Documents" section of the Mayo Clinic IRB application.
- The PI must obtain and include documentation (preferably in the English language) of the following in the Supporting Documents section of the Mayo Clinic IRB application:
    - Review and approval by the local IRB at the locality where the research will be performed,
    - Documentation of the non-U.S. institution/site's contact information, including the name of the Chair of the local IRB, the mailing address; email address(es), and telephone number(s), and
    - A letter of agreement signed by the appropriate institutional official for the non-U.S. institution/site where the research will be performed.
- The PI must detail the consent process in the Mayo Clinic IRB application and within the protocol (see Mayo Clinic IRB policy titled Informed Consent and the Research Subject).
- The PI must provide the Mayo Clinic IRB with a consent form translated into the language appropriate to the location of the research and the subject population; an English language translation, and a letter of certification of translation. All consent documents and subject contact materials intended for use at a non-U.S. institution/site must be approved for use at that site by the Mayo Clinic IRB.
- The PI must provide the Mayo Clinic IRB documentation of the local IRB initial reviews and post-approval determinations relating to continuing review, modifications, and reportable events.
- The PI is responsible for the timely reporting of reportable events to both the Mayo Clinic and the local IRB. The PI must provide documentation to the Mayo Clinic IRB of the findings of the local IRB. See the Mayo Clinic policy titled Submitting a Reportable Event to the IRB.
- The PI is responsible for demonstrating appropriate expertise and knowledge of the country and culture in which the research will be conducted including local laws, regulations, customs, and practices (see OHRP document International Compilation of Human Research Protections).
- The PI will provide documentation to the Mayo Clinic IRB that adequately addresses the PI's qualifications to conduct research at the non-U.S. institution/site. Include this documentation in the "Supporting Documents" section of the Mayo Clinic IRB application.
    - Documentation of investigator qualifications may be contained within the Curriculum Vitae (CV), for example, or may include other proof (letter, transcript, certificate of attendance)

of intercultural training/education/orientation specific to the region where the research will be conducted.
    - The PI and study team members may not perform interventional research procedures without appropriate professional licensure to do so within the non-U.S. institution/site. If applicable, the PI will provide the IRB with documentation of exemption from licensure.

IRB Responsibilities

The Mayo Clinic IRB, through its policies and procedures, will ensure the safe and ethical conduct of international research, including:

- Conducting the review with the appropriate expertise and knowledge of the country, either through IRB membership or consultants. For assistance in meeting this requirement, the IRB may contact:
    - Mayo Clinic International Services Representatives
        - Mayo Clinic Rochester: (77) 4-4161
        - Mayo Clinic Arizona: (79) 2-7101
        - Mayo Clinic Florida: (78) 3-7000
- Review of the qualifications of the researchers who will be at the institution/site conducting the research.
- Initial review, continuing review, and review of modifications and reportable events.
- Review of the proposed consent process and consent form, including cultural, language and translation issues, and a letter of certification from a translator, as necessary. All consent documents and subject contact materials intended for use at a non-U.S. institution/site must be approved for use at that site by the Mayo Clinic IRB.
- Post-approval monitoring: The Mayo Clinic IRB may designate monitoring activities commensurate with the risks associated with the research and the level of involvement of Mayo Clinic, or the level of involvement of another entity for which the Mayo Clinic IRB is the IRB of record, for example, a continuing review period of less than one year, use of a data safety monitoring board, or on-site auditing of investigators.
- The Mayo Clinic IRB will seek the advice of legal counsel, as necessary.

Policy Notes

Locating institutions/organizations with registered IRBs and FWAs

1. Navigate to the DHHS online database
2. Choose one of the tabs: "IORGs, IRBs, FWAs, or Documents Received in Last 60 Days", as applicable.
3. Choose "Advanced Search".
4. Search by country, institution/organization name, etc.

Instructions for Mayo Clinic employees to complete the CITI training course

- Access the CITI website.
- To register as a "New User" follow the steps "Register Here" and complete registration steps a-g:
    - To select your institution or organization: Click the drop box for the "Participating Institutions" and choose Mayo Clinic.
    - Create Your Username (Use your Mayo LAN ID) and Password. Record this information as you will need it in the future for refresher or additional courses.

- Complete the additional" Member Information". Enter your role in human subjects research field.
- When asked to select a Learner group, select "International Research".
- Complete the subsequent screen.
- You will be directed to the "Learner's Main Menu". To begin the course, click "Enter" under "Status of My Courses". Click on the next required module to begin.
- After completing each module, you will need to take a short quiz. The results of the quiz will be collated and a minimum score of 80% is needed to pass. There is not a limit on the number of times you may retake the quizzes.
- It is not necessary to complete the entire course at once. To log back in, access the website and enter your username and password. You will be directed back to the Learner's Main Menu.
- After completing the entire course, follow the online instructions for acquiring a certificate of completion or completion report.

Related Procedures

N/A

Related Documents

Eligibility as Principal Investigator Policy

General Data Protection Regulation Compliance Policy

Informed Consent and the Research Subject

Knowledge of the Local (domestic and international) Research Context

Submitting a Reportable Event to the IRB

Definitions

N/A

References

Association for the Accreditation of Human Research Protection Programs (AAHRPP), version 10/29/2020

Owner

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Contact

Michelle K. Daiss, Heidi M. Hanf

Revision History

Date	Synopsis of Change
04/28/2021	Outside of scheduled review. Updated Related Documents section.
11/02/2020	Scheduled review. Updated owner, Contact and minor changes. Hyperlinks updated. Minor edits by Policy office. Added GDPR language.
03/23/2018	Updated to new Policy, added purpose statement, no other changes due to AAHRPP Accreditation cycle.
03/22/2016	1) Added "Revision History" and 2) Expanded scope to include research for which the Mayo Clinic IRB is the IRB of record and edited text to clarify requirements and processes for Mayo Clinic and non-Mayo Clinic research teams.

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