SOP 305: Collaboration with External Researchers

Terms and Abbreviations

CTSI: Clinical and Translational Science Institute of Southeastern Wisconsin; a consortium of regional organizations whose mission is to advance the health of the community through research and discovery.
FWA: Federalwide Assurance; a formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.
HHS: Health and Human Services; a department of the US government whose responsibility is the protection of the health of Americans
HRPP: Human Research Protection Program
IAA: IRB Authorization Agreement; an agreement between two institutions regarding IRB oversight of a study.
IIA: Individual Investigator Agreement; an agreement between an institution and an individual regarding IRB oversight of a study.
IO: Institutional Official; the individual who is legally authorized to act for the institution and ensures the effective functioning of the IRB.
IRB: Institutional Review Board
IRB office staff: the IRB Manager, IRB Administrator, and any other IRB office staff, either collectively or individually
SMART IRB: An organization dedicated to streamlining reliance request process and enhancing collaboration between institutions, through a single SMART IRB Agreement and an Online Reliance System.
UWM: University of Wisconsin – Milwaukee

Overview

When research involves multiple institutions, UWM may agree to rely on another institution's IRB for review of the research or may accept responsibility for overseeing the research on behalf of another institution. Known as a "reliance agreement," "deferral agreement," or "single IRB review," the intent is to ease administrative burden on both the researcher and the IRB by having a single IRB oversee a study, rather than requiring multiple IRBs to review it.

The decision whether to enter into a reliance agreements and which institution will oversee a given study ultimately rests with the Institutional Official. Researchers do not have the authority to make this decision and should always consult with the IRB office prior to making any verbal or written statements regarding study oversight.

Single IRB review is required for federally funded, non-exempt studies, except in the following cases:

- Activities that occur outside the United States. Single IRB approval is required only for that portion of the research that is conducted in the United States.
- Where additional IRB reviews are required by law, as with studies involving the Veterans Affairs (VA) or where tribal laws passed by the official governing body of an American Indian or Alaska Native tribe require separate IRB review.
- Where the research activities differ between sites. Single IRB review is only required for activities that are the same across multiple sites.

If an external collaborator is not affiliated with any other institution holding an FWA, then UWM may accept responsibility for that researcher's participation in the study through use of an Individual Investigator Agreement (IIA).

Details and Procedures

General process for establishing a Reliance Agreement

1. UWM faculty, staff, or students wishing to conduct human subjects research in collaboration with an external researcher must submit a formal request to the IRB Office. The IRB needs the following information:
    a. Study title
    b. Funding source
    c. Brief summary of the study aims and procedures
    d. Names of all involved researchers, their home institution(s), and the specific study procedures (recruitment, consent, data analysis, etc.) each individual will do.
    e. Contact information for the responsible individual(s) at the other institution(s) who can arrange a reliance agreement (normally someone in the institution's IRB/HRPP office).
2. IRB office staff reviews the request and works with the other institutions to determine whether a reliance agreement is desired and, if so, which institution will accept IRB oversight for the study. The decision will be based on the following:
    a. Willingness of the other institution. UWM generally will enter into a reliance agreement with any willing institution, but some institutions will only enter into reliance agreements for certain review levels or for federally funded studies.
    b. If there is funding, which institution is the direct awardee. In most cases, the UWM IRB will oversee the study if UWM is the direct awardee of a grant.
    c. Location where the majority of study activities will occur. If UWM researchers will be primarily responsible for study activities, then the UWM IRB usually prefers to oversee the study. If only a small percentage of study activities will be performed by the UWM researchers, it is often preferable to have the other institution oversee.
    d. Qualifications of the respective IRBs to review the study. If the UWM IRB members do not have expertise to review a given type of research (e.g. studies involving medical procedures), it is preferable to allow an IRB with greater expertise to oversee on UWM's behalf.
    e. The UWM IRB will not rely on any institution that does not have an active FWA.

3. If the institutions determine that there will not be a reliance agreement, IRB office staff will notify the submitter that they must submit a full protocol to each institution separately.
4. If the other institution is amenable to entering into a reliance agreement, IRB office staff will work with the other institution to execute the agreement. The process varies depending on which of the following groups is involved.
    a. CTSI Partner institutions: If all involved institutions are CTSI partners, IRB office staff establish the agreement via email with the other institution(s), referencing the SEWIC Agreement.
    b. SMART IRB: If a request is made through the SMART IRB platform, IRB office staff either accept or decline the review request within the platform. If the other institution has a SMART IRB addendum, IRB office staff review the addendum and may consult with UWM's Legal Affairs department to determine the appropriateness of the terms.
    c. All others: The IRB Office staff either create an IAA for the specific study or use the IAA provided by the other institution. IRB office staff may consult with UWM's Legal Affairs department for agreements that deviate from the standard UWM template language. IRB office staff then route the IAA to the IO for signature. The IO may sign, ask for additional information, or decline to enter into the agreement.
5. Once the reliance agreement is complete, IRB office staff will notify the submitter. If IRB approval has not yet been obtained, IRB office staff will instruct the submitter to submit their research proposal to the appropriate IRB for review.
6. Official documentation of the reliance agreement will be kept with the IRB study files.
7. The IRB and IO are notified of all reliance agreements in writing.

Exempt Research

Often it is not known at the initial request stage whether a study will qualify for exempt status or not. Furthermore, some exempt categories require limited IRB review. Therefore, UWM will follow the same process outlined above to enter into agreements for relying on another institution's exempt determination / limited IRB review or agreeing to provide an exempt determination / limited IRB review on behalf of another institution.

SMART IRB

A request can be initiated through SMART IRB for reliance requests with any participating institution. The criteria affecting UWM's decision are the same as outlined above, but the reliance is executed within the SMART IRB platform. The current list of participating institutions, access to the platform, and instructions for use can be found on the SMART IRB website.

General process for establishing an IIA

An IIA is a legal mechanism for ensuring the appropriate conduct of a study by an external researcher. This is invoked when the researcher does not belong to an institution with its own IRB oversight and/or FWA.

1. When a study is identified involving an external researcher who is not affiliated with an institution that can enter into an IAA, IRB office staff complete the IIA form for the specific study and send it to the researcher for signature.

a. For HHS-funded studies, multiple individuals from the same institution may sign IIAs with UWM. These may be done as separate agreements, or a single agreement with the names and signatures of all external researchers. This process may also be followed for other funding agencies, but the specific agency should be consulted before proceeding to ensure that it is allowed.

2. Once the signed copy is received, IRB office staff route the IIA to the IO for signature. The IO may sign, ask for additional information, or decline to enter into the agreement.
3. Failure of the external researcher to comply with the terms of the agreement can result in legal action by UWM.

References

CTSI: https://ctsi.mcw.edu/about/history/

SMART IRB: https://smartirb.org/

45 CFR 46.114: Cooperative Research

Appendices

305.1 IAA request form for CTSI partners

305.2 IAA generic request form

305.3 IAA template

305.4 IIA template

Revision History

Version	Date	Summary of Changes
1	1 Feb 2022	Initial version