Institutional Review Board (IRB)

IRB Guidance on Reliance Agreements

Scope: This guidance applies to all human subject's research studies which propose involve an external entity.

Background:

An institution is engaged in human subject's research if:

a. It participates in recruitment of potential participants and/or answers questions about the study.
b. It interacts with potential participants in the enrollment or informed consent process.
c. It participates in the collection of study data from participants or has access to identifiable participant information/data.
d. The funding proposal identifies its involvement in research activities.

What is an Institutional Review Board (IRB) Authorization Agreement?

An IRB Authorization Agreement (IAA) is an agreement between two institutions engaged in human subject's research that permits one institution's IRB to cede review to another institution's IRB, therefore executing reliance. The IAA allows one IRB to conduct a full review of a research project rather than requiring both IRBs to conduct a full review.

What is an Individual Investigator Agreement?

An Individual Investigator Agreement (IIA) is an agreement between an institution with Federalwide Assurance (FWA) conducting human subject's research and a collaborating individual investigator (*collaborating independent investigator and/or collaborating institutional investigator*). The IIA allows the FWA to be extended to an individual and documents the investigator(s) agreement to fulfill specified responsibilities. IIAs provide an alternative for non-FWA individuals who do not routine conduct research to participate in human subject's research *(e.g., private practice, church, school, etc.).*

A collaborating independent investigator is:

a. not an employee or agent of UMass – Dartmouth (UMassD).
b. not an employee of, nor conducting on behalf of, any institution with respect to their involvement in the research **AND**
c. conducting collaborative research activities outside of UMassD.

A collaborating institutional investigator is:

a. not an employee or agent of UMassD but rather employed by, or an agent of, a non-FWA institution. **AND**
b. conducting collaborative research activities outside of UMassD.

Elements for Consideration:

1. Contact the IRB via email: irb.research@umassd.edu, to request confirmation the study meets the criteria to require a Reliance Agreement. The IRB will require the following information:
   a. Who is sponsoring/funding the study?
   b. What procedures will be conducted at or by UMassD vs. at and/or by the external entity?
   c. Who is the external entity's point of contact?
2. If appropriate, the IRB will issue the appropriate form (IAA or IIA) for the collaborating institution/investigator to complete and request relevant documentation is provided.
   a. For an IAA, the UMassD IRB will ask to meet with the UMassD investigators, collaborating investigators, and the external IRB's representative to confirm the need for an IAA reliance agreement. If necessary, both IRB representatives will ensure corresponding IRB Signatory Official sign the agreement.
   b. For an IIA, in addition to the completed and signed form, provide:
      i. For collaborating *institutional* investigators, the appropriate authorities at the non-FWA institution must provide a letter of support stating the conduct of the research is permitted at their institution/location.
      ii. For collaborating *independant* investigators, provide their current Curriculum Vitae (CV) or resume.
3. Include all collaborating investigator(s) on the UMassD IRB application as personnel and explain their role.
4. All collaborating investigators must complete the appropriate CITI training course or applicable course; certification should be included with the IRB application. The IRB requires investigators to have the required training completed in an appropriate human subject's protection training before approval can be issued.

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FREQUENTLY ASKED QUESTIONS (FAQ):

1. What is the purpose of a reliance agreeement?
A reliance agreement outlines the responsibilities of the institution conducting the review and the institution relying on the reviewing IRB. Note, when the UMassD IRB cedes review to another IRB, the UMassD IRB is still responsible for ensuring local researchers meet requirements for human subject's research training, reporting of potential conflicts of interest, and compliance with applicable local laws. Therefore, even when the UMassD IRB cedes review to another IRB, submission to the UMassD IRB is still required to ensure local compliance is upheld.

2. Do federal regulations require reliance agreements for Exempt Studies?
No, reliance agreements are not required for exempt studies; instead, the IRB requires collection of a letter of support from the external entity to confirm the acceptability of external site use.

3. What if I am only sharing IRB-approved recruitment materials and will not be involved in research?
If an individual intends to share non-UMassD IRB-approved recruitment materials (such as handing out a flyer or forwarding an email) and will not be involved in answering questions about the study nor obtaining informed consent, they must submit an IRB application, approved materials, and consult with the IRB about the necessary agreement.

4. What if I am only receiving unidentifiable data?
If an individual is only receiving de-identified data and will not have a way to re-identify that data (e.g., through access to a code key or via indirect identifiers), they are not considered to be engaged in research.

5. What elements are needed when submitting a reliance agreement request?
The IRB needs to know the name of the external entity, if the investigator is affiliated to any institution, whether the external investigator is engaged in the research, what activities will occur at each site, the risk level of the research, and whether the study has received funding. If the study is funded, the IRB will also need to review the funding proposal. If the study has already been reviewed by an external IRB, the UMassD IRB will need to review the approved protocol and any other relevant study documents such as the application, consent forms, recruitment materials and any other participant facing materials.

6. How long is the review process?
The IRB recognizes all research is important and wants to facilitate a smooth and quick process for all investigators. At this time, the approximate timeline varies based on the depth of information provided and the response time of the external entities. Once a Reliance Agreement request has been submitted, the IRB will review it within 5 business days. After review, the IRB will either ask for additional information or, if no additional information is needed, begin the process of executing the agreement. The time frame from submitting the Reliance Agreement form to a signed agreement is 1-4 weeks depending on the type of agreement.

7. Who signs these agreements?
For an IAA, both Institutional Officials from the reviewing and relying IRB must sign the Agreement. For an IIA, the Agreement must be signed by the Collaborating Investigator, the UMassD Principal Investigator, and the UMassD Institutional Official.

8. What if the study is federally funded?
Federally funded studies which require multiple entities to engage in human subject's research, are subject to additional single IRB (sIRB) considerations. The establishment of an sIRB requires the execution of reliance agreements between entities involved.

Adapted with gratitude from the following references:
1. Office of Human Research Protection. *OHRP Guidance on Engagement of Institutions in Human Subjects Research.*
2. Harvard University. Human Research Protection Program. *Collaborative Research with Another Institution.*
3. Yale University. Human Research Protection Program. *Reliance Agreements.*
4. Michigan State University. Human Research Protection Program. *Multi-Site Research and IRB Reliance.*