Guidance on Authorization Agreement Procedures

**Expedited** and **full review** human subjects research involving multiple institutions *may not* require approval from each Institutional Review Board (IRB). The Office for Human Research Protections (OHRP) regulations allow for one institution to rely on the IRB of another institution through an **Authorization Agreement**. To be eligible for participation in an authorization agreement, the institution must have both an active Federalwide Assurance (FWA) and an active IRB. Despite eligibility, some institutions legally cannot or may choose not to enter into an authorization agreement. At Marquette University (MU), the Institutional Official (IO) makes the final determination whether or not to participate in an authorization agreement.

There are two ways of executing authorization agreements: 1) MU relies on another institution’s IRB, or 2) Another institution relies on MU’s IRB.

**Procedure for requesting an Authorization Agreement for MU to rely on another institution’s IRB:**

1. Download the appropriate request form from MU’s Office of Research Compliance (ORC) website.
   a. “Request MU IRB rely on another IRB”
2. Submit the following to the ORC:
   a. Completed MU Authorization Agreement Request Form
   b. Copy of proposal, tools, and consent submitted to/approved by other institution
   c. Copy of approval letter from other institution, if approved
3. MU’s ORC will review the protocol and identify any areas of concern, verify the other institution’s FWA and IRB in OHRP’s online registry, and will contact the other institution to find out whether or not the institution would be willing to participate in an authorization agreement.
4. MU’s ORC will then forward all documentation to the MU IO for determination on Marquette’s behalf.
5. If the IO indicates that an authorization agreement is acceptable, MU’s ORC will draft the authorization agreement unless the other institution requires use of their agreement form.
6. IOs will sign the agreement:
   a. MU’s ORC will procure MU IO’s signature. Document will then be scanned and emailed to other institution’s contact person.
      i. If it is more time efficient, other institution may procure signatures first.
   b. Other institution’s IO will sign document.
      i. Please note that this step can take a week to a month to several months, depending on the institution. Some institutions are slower than others and may require approval by multiple parties or departments before signing.
7. Once document is returned to MU, MU’s ORC updates MU’s FWA to indicate reliance on the other institution’s IRB.
8. MU’s ORC notifies PI that authorization agreement is in place and research can begin.
9. It is the PI’s responsibility to ensure that MU’s IRB is kept up-to-date on any key issues or concerns.
   a. The PI must forward a copy of the annual IRB review approval letter.
   b. The PI must notify the MU IRB if there have been any adverse events, unexpected problems, deviations, or other incidents regarding the protocol.
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Procedure for requesting Authorization Agreement for other institution to rely on MU’s IRB:

1. Download the appropriate request form from the ORC website.
   a. “Request another IRB to rely on MU IRB”
2. Submit the following to the Office of Research Compliance:
   a. Completed MU Authorization Agreement Request Form
   b. Protocol summary form, research tools, consent form, and any other required documentation
3. If MU has not already heard from the other institution, MU’s ORC will contact the other institution to find out whether or not they are agreeable to an authorization agreement.
4. MU’s ORC will review the protocol under standard review procedures.
5. MU’s ORC will verify the other institution’s FWA and IRB in OHRP’s online registry and forward all documentation to the MU IO for determination on Marquette’s behalf.
6. If MU IO indicates that an authorization agreement is acceptable, MU’s ORC will draft the authorization agreement unless the other institution requires use of their agreement form.
7. IOs will sign the agreement:
   a. MU’s ORC will procure MU IO’s signature. Document will then be scanned and emailed to other institution’s contact person.
      i. If it is more time efficient, other institution may procure signatures first.
   b. Other institution’s IO will sign document.
      i. Please note that this step can take a week to a month to several months, depending on the institution. Some institutions are slower than others, and some institutions require approval by multiple parties or departments before signing.
8. Once document is returned to MU, the other institution must update its FWA to indicate reliance on MU’s IRB.
9. The PI will be notified when the authorization agreement is executed, and when the protocol itself is approved. Both pieces must be in place for the research to begin.
10. It is the PI’s responsibility to ensure that the other institution’s IRB is kept up-to-date on any key issues or concerns.
11. The protocol will remain under normal MU IRB oversight.

For more information on Authorization Agreements, please contact the Office of Research Compliance at 414-288-1479 or orc@marquette.edu.