 <p>MARQUETTE UNIVERSITY Office of Research Compliance</p>	SOP	Title	Date	Page
	IRB-110	IRB Agreement/Reliance/Deferral and Single IRB Requests	July 2018	1 of 3

1. PURPOSE

1.1. This policy establishes the requirements for MU relying upon an external IRB or an external IRB relying upon MU to oversee IRB activities.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. Unless instructed to do otherwise by the ORC, the following procedures are required to request an external IRB to rely upon MU IRB:

3.1.1. Download the appropriate request form from MU's Office of Research Compliance (ORC) website.

3.1.2. Submit the following to the ORC:

- Completed the reliance request form
- Copy of proposal, tools, and consent submitted to/approved by other institution
- If applicable, copy of approval letter from other institution


3.1.3. The ORC will review the submitted materials and identify any areas of concern.

3.1.4. If applicable, the ORC will verify the other institution's FWA and IRB in OHRP's online registry, and will contact the other institution to determine whether or not the institution would be willing to participate in an authorization agreement. Part of the determination may include local context, training requirements, and institution specific requirements.

3.1.5. After MU and the external IRB have determined an IRB agreement is possible, an authorization agreement will be drafted and processed, along with other supporting materials, for the IO or his or her designee's approval.

3.1.6. If it is more time efficient, the external IRB may procure signatures first.

3.1.7. The ORC will notify the MU PI that an IRB agreement is in place and research can begin or if there are any conditions that are required to be fulfilled prior to or during the research.

	SOP	Title	Date	Page
	IRB-110	IRB Agreement/Reliance/Deferral and Single IRB Requests	July 2018	2 of 3

3.1.8. Once the reliance agreement is complete, the MU PI and faculty advisor is responsible for:

- Ensuring the MU IRB approved protocol includes the activities from the site that is relying upon MU
- Ensuring the MU IRB approved protocol includes list the research personnel from the site that is relying upon MU
- Ensuring research personnel from the relying site have appropriate training
- Communicating promptly to MU IRB any reportable events taking place at or affecting the site that is relying upon MU
- Communicating/sharing of relevant MU IRB approved documents and notifications

3.2. Unless instructed to do otherwise by the ORC, the following procedures are required to request MU IRB to rely upon an external IRB:

3.2.1. Download the appropriate request form from MU's Office of Research Compliance (ORC) website.


3.2.2. Submit the following to the ORC:

- Completed the reliance request form
- If the project has not already been submitted to MU IRB, the proposal, tools, and recruitment and consent documents
- Any relevant communication from the external IRB regarding a possible IRB reliance request

3.2.3. The ORC will review the submitted materials and identify any areas of concern.

3.2.4. If applicable, the ORC will verify the other institution's FWA and IRB in OHRP's online registry, and will contact the other institution to determine whether or not the institution would be willing to participate in an authorization agreement. Part of the determination may include local context, training requirements, and institution specific requirements.

3.2.5. After MU and the external IRB have determined an IRB agreement is possible, an authorization agreement will be drafted and processed, along with other supporting materials, for the IO or his or her designee's approval.

 MARQUETTE UNIVERSITY Office of Research Compliance	SOP	Title	Date	Page
	IRB-110	IRB Agreement/Reliance/Deferral and Single IRB Requests	July 2018	3 of 3

3.2.6. If it is more time efficient, the external IRB may procure signatures first.

3.2.7. The ORC will notify the MU PI that an IRB agreement is in place and if appropriate, notification that research can begin or if there are any conditions that are required to be fulfilled prior to or during the research.

3.2.8. The MU PI or faculty advisor is responsible for communicating any relevant information, such as reportable events or problems taking place at or affecting MU.

3.2.9. The MU PI or faculty advisor is responsible for notifying MU IRB if the IRB MU is relying upon has closed or completed the study, or has suspended or terminated IRB approval.

3.3. The ORC may contact the Institutional Official or designee, IRB members, and/or other resources for assistance during this process.

3.4. If necessary, the ORC will update MU's FWA to indicate reliance on the other institution's IRB.

3.5. Completing an IRB agreement can take a week to a month or longer depending on the institution. Factors contributing whether an IRB agreement can be completed, or how long it would take to be complete are:

- Source of funding
- Types of activities taking place
- Where activities are taking place
- Other departmental or office approvals

3.6. IRB Agreements are limited to IRB review, and do not include ancillary committee reviews falling outside the scope of the IRB.