 <p><b>MARQUETTE</b> UNIVERSITY Office of Research Compliance</p>	SOP	Title	Date	Page
	IRB-060	IRB Record retention and documentation	July 2018	1 of 2

## 1. PURPOSE

1.1. This policy establishes the record retention of the IRB and PI and the documentation of findings to the PI.

## 2. REVISIONS FROM PREVIOUS VERSION

2.1. None

## 3. POLICY

### 3.1. IRB record retention:

3.1.1. The IRB's files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments, and reportable events.


3.1.2. The IRB will maintain and retain the appropriate records for each research study, consistent with federal regulations and MU's records retention policies.

3.1.3. Research study records may consist of electronic and non-electronic records.

### 3.2. IRB documentation:

3.2.1. Study-specific documents will be prepared, maintained and retained in a secure location. Documents to be retained include:

- Original applications for review/determination
- IRB reviewer comments, checklists, and review sheets
- Agendas and minutes from convened IRB meetings
- Requests for single IRB, authorization agreements, and reliance requests.
- For nonexempt research involving human subjects covered by the Common Rule, or exempt research for which limited IRB review takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol)
- Correspondence as it relates to the submission and review of initial applications, amendments, continuing reviews, reportable events, and study completions

 <b>MARQUETTE</b> UNIVERSITY Office of Research Compliance	<b>SOP</b>	<b>Title</b>	<b>Date</b>	<b>Page</b>
	IRB-060	IRB Record retention and documentation	July 2018	2 of 2

### 3.3. PI record retention:

- 3.3.1. The PI will maintain and retain the appropriate records for each research study, consistent with federal regulations and MU's records retention policies.
- 3.3.2. Research study records may consist of electronic and non-electronic records and will be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.
- 3.3.3. When authorization to use or disclose Protected Health Information (PHI) is required from a research subject A copy of the signed authorization form, or consent form containing HIPAA required elements should be kept for a minimum of six (6) years from the date it was obtained.