| | | SOP |
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| **Department** | **Title** | **Dates** |
| Research Integrity and Protection | Materials for Human Subject Research Review | Effective: 12/22/2017 |
| | | Approved: 12/18/2017 |
| **SOP ID** | | Last Revised: n/a |
| IRB-SOP-105 | | Expiration: n/a |

**PURPOSE**

The purpose of this standard operating procedure is to outline the documentation requirements when seeking IRB approval through the initial, continuing, or amendment review processes.
These requirements apply when the AWRI IRB serves as the IRB of record. To enable the IRB to meet their regulatory obligations, RI&P staff and IRB member rely on this documentation to systemically evaluate each research study to assure the protection of human subjects and adhere to the regulatory requirements.

**SCOPE**

This procedure applies to research conducted at Ascension Wisconsin and all researchers, study teams and RI&P staff.

**DEFINITIONS**

**Investigator or Researcher** is an individual who participates in the design, conduct, analysis or reporting of research activities. If the research is conducted by a team of individuals, the investigator is the responsible leader of the team and may be called the Principal Investigator (PI).

**PROCEDURES**

1. **Submission of Materials**
   - **1.1.** Investigators are responsible for preparing and submitting the materials for review.
   - **1.2.** Investigators are expected to use the forms and guidance provided by Research Integrity and Protection (RI&P) and to provide sufficient information to RI&P and the IRB so that specific required determinations can be made and it can be determined, as appropriate, the type of review is required and whether the applicable criteria for IRB approval have been met.
   - **1.3.** Submissions to RI&P and the IRB must be submitted through Mentor.

2. **Materials Required for IRB Review**
   - **2.1.** Materials below provided by the investigator, when applicable:
     - **2.1.1.** Initial applications
       - Application form and study information in Mentor
       - Application addendums
       - Consent/assent/parental permission documents
       - HIPAA authorization/ waiver/Data Use Agreement
       - Recruiting and screening materials
       - Data collection instruments (including questionnaires, etc.)
       - Investigator's Drug Brochure or Package Insert
       - Device Brochure and/or other device information
       - Documentation regarding need for/approval of for IND, IDE, or HDE
       - Protocol (from Industry Sponsor or Investigator Authored)

- Relevant grant application for federally funded research or contract, as requested
- Any Financial Conflict of Interest Management Plan
- For Multi-center studies where the Local PI is the Lead Investigator for the study, information about study oversight and operations (data coordinating center activities)
- Any other materials provided by the investigator

**2.1.2.** Continuing review
- Continuing Report Form and Mentor Status update, including a summary of activity since the last review
- Adverse Event and Protocol Deviation Logs
- Publications or interim analysis
- Relevant post-approval reports (e.g., Data and Safety Monitoring, audit reports)
- Redacted consent forms used for vulnerable population, as requested in the continuing report form
- Any other materials provided by the investigator

**2.1.3.** Amendment/modification (changes outlined via tracked changes or summary)
- Amendment form and description in Mentor
- New or revised study documents (e.g. Consent, Protocol, Surveys)
- New or revised local conduct (e.g. recruitment plan, consent procedures)
- Relevant post-approval reports (e.g., Data and Safety Monitoring Reports)
- Any other materials provided by the investigator

**2.1.4.** Reportable Events and other information
- IRB form and description in Mentor
- Any other materials provided by the investigator

**2.2.** Additional material from IRB staff

**2.2.1.** IRB correspondence, including Investigator response, regarding the submission

**2.2.2.** Completed Pre-review Checklist and any other information deemed useful by IRB staff (e.g., a policy or SOP)

**2.2.3.** Any information or assessment provided in advance by the primary reviewer or a consultant

**2.2.4.** In addition, the IRB reviewer has access to the complete IRB protocol file in Mentor.

**REFERENCES**

45 CFR 46.109 21 CFR 56.108(a)(4), 45 CFR 46.110
21 CFR 312 45 CFR 46.111, 21 CFR 812 45 CFR 46.115
IRB SOP: Human Subject Research Exempt from IRB Review

**RELATED MATERIALS**

None

**REVISION HISTORY**

| Version # | Date Revised | Reason for/Brief Description of Change | Revised By |
|---|---|---|---|
| 01 | 12/6/2017 | New- Initial Integration Update | J. Blundon |