SOP

Department	Title	Dates
Research Integrity and Protection	Policies and Procedures	Effective: 5/31/2018
		Approved: 5/29/2018
SOP ID		Last Revised: 5/22/2018
IRB-SOP-006		Expiration: n/a

PURPOSE

This SOP establishes the procedures for developing, implementing and revising policies and procedures for the Ascension Wisconsin Institutional Review Board (IRB) and Research Integrity and Protection (RI&P).

SCOPE:

This SOP applies to Research Integrity and Protection, including all IRBs.

DEFINITIONS:

Assurance of Compliance or Federalwide Assurance (FWA) A legally binding written document that commits an institution to complying with the Federal Policy (Common Rule) and other applicable Federal and VA standards for the protection of human subjects.

Institutional Official (IO) A high-level institutional official who has the authority to represent the institution named on a FWA as well as the institutional components listed in the FWA. The individual should be at a level of responsibility that would allow authorization of necessary administrative or legal action should that be required. The IO must assure that human subject research to which the FWA applies is conducted in accordance with the terms of the FWA.

Policy A guiding principle of operation, broad decision-making or service.

PolicyStat The institutional system used to write, approve and manage policies. Institutional policies and procedures are followed when using PolicyStat.

Standard Operating Procedure (SOP) The term used by RI&P to refer to documents containing RI&P and IRB policies and procedures.

PROCESS

1. **Responsibilities**
   - **1.1.** The Institutional Official is responsible for reviewing all IRB and IRB-relevant policies and SOPs, prior to implementation.
   - **1.2.** The RI&P Director is responsible for the following areas, though any of these responsibilities may be delegated to other RI&P staff on a routine or ad hoc basis:
     - **1.2.1.** Overall management of RI&P and IRB policies and SOPs. This includes: drafting new and revised documents; obtaining consultation and feedback; obtaining Institutional Official approval; and communication.

1.2.2. Promoting and ensuring consistency in interpretation and implementation of the policies and procedures.

1.3. All RI&P staff must follow implemented RI&P and IRB policies and procedures.

1.4. All IRB members are responsible for following implemented IRB policies and procedures.

2. Policies and SOP Development

2.1. SOPs are written using the standard template. Variations in structure and content are permissible when appropriate for the content or for ensuring clarity. Research policies follow the institutionally required format within PolicyStat.

2.2. Content is drafted by the RI&P Director or designee.

2.3. Consultation and feedback are obtained as appropriate to the content.

2.3.1. This may include (but is not limited to):

- The AWRI Advisory Board or Scientific Research Councils
- IRB members
- RI&P management and staff
- Other departments, such as Clinical Research, General Counsel, Corporate Responsibility

2.3.2. Consultation and feedback may be obtained through any methods and mechanisms that seem appropriate. For example, emailed draft documents, presentations at staff, IRB or other meetings or discussion sessions.

3. Approval Process

3.1. The RI&P Director obtains approval from the IO by providing the IO with a copy of the final SOP document. This may be preceded or accompanied by a summary of the content, the feedback and consultation obtained implications, regulatory basis, etc.

3.2. The RI&P Director documents IO approval and notes this as the “date approved” on the SOP.

3.3. Research policies are approved through PolicyStat.

4. Implementation and Communication

4.1. SOPs are considered to be implemented when they are posted on the RI&P website/electronic IRB system. Policies are implemented when posted in PolicyStat.

4.2. SOPs and policies are effective the date listed in the document.

4.3. SOPs are formally distributed to their audiences (e.g. staff, IRB members, researchers, etc.) by being posted on RI&P’s website, notices in the eIRB system, and/or in the eNewsletter. More significant updates may be communicated through email notification using the internal or eIRB system or by presentations at staff, IRB or other meetings, discussion sessions, etc.

5. Management of SOPs

5.1. R&IP, including IRB and Research Education and Quality Management, and maintained by the RI&P Director.

5.2. Implemented documents are stored electronically in the RI&P shared drive.

5.3. SOPs are revised as needed, which is generally at least once every two years.

5.3.1. A revision history is included within each document for tracking.

5.4. SOPs may be retired for many possible reasons, such as regulatory changes that eliminate the need for the SOP.

5.4.1. The RI&P Director is responsible for making the decision to retire a SOP.

5.4.2. The retirement process consists of: Removing the SOP from the website/ eIRB, moving the SOP into the "Archived" section of the Document Library; updating the SOP management list.

6. RI&P and IRB Practices

6.1. Staff and IRB members may occasionally develop practices for doing certain operations or handling certain issues. Such practices are not considered official RI&P or IRB SOPs, even when they exist in writing and have been widely adopted.

6.2. Practices must be consistent with implemented HSD or IRB SOPs.

6.3. Practices that arise out of interpretation of regulations or policies should be evaluated by RI&P management for consistency with existing SOPs and the possible need for a new or revised SOP.

6.4. Practices should not be construed as limitations on the flexibility or range of possibilities inherent in regulations and in official SOPs.

REFERNCES

None

RELATED MATERIAL

None

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	5/25/2018	New- Initial Integration Update	J. Blundon-Kirchen