Department	**Title**	**Dates**
Research Integrity and Protection	Transfer of IRB Oversight	Effective: 10/23/2017
		Approved: 4/25/2017
SOP ID		Last Revised: 10/23/2017
IRB-SOP-809		Expiration: n/a

SOP

PURPOSE

If it becomes necessary to transfer the IRB review responsibility from one IRB to another, it is important for the transfer to occur in an orderly way that assures continuous IRB oversight with no lapse in either IRB approval or the protection of human subjects, and with minimal disruption of research activities. This policy outlines the steps taken to transfer IRB oversight between the Ascension IRB and non-Ascension IRB.

SCOPE

Transfer of review responsibility between an Ascension IRB and non-Ascension IRB.

DEFINITIONS

Receiving IRB: This is the IRB that will accept oversight.

Original IRB: This is the IRB that initially had IRB oversight.

PROCESS

1. Transfer of IRB oversight will be considered under justifiable circumstances. Examples may include closure of the IRB, a researcher moves to a new institution or minimization of duplicate effort.

2. All transfer decisions must be approved in advance by IRB leadership, including the Institutional Official (IO).

3. The transfer process is approved and managed by Research Integrity and Protection staff, generally the Director, who will work with the Investigator and original IRB.

4. A transfer plan will be developed for each transfer outlining the specific responsibilities of each IRB involved.

4.1. The transfer plan will include the following:

- Identifying those studies for which IRB oversight is being transferred
- Ensuring the availability and retention of pertinent records
- Establishing an effective date for transfer of oversight, including records, for the clinical investigation(s)
- Conducting a review of the study(ies) by the receiving IRB, where appropriate, before it accepts responsibility for the study(ies)
- Confirming or establishing the date for the next continuing review
- Determining whether the consent form needs to be revised
- Notifying the key parties
- Updating IRB registration information

5. Request to transfer IRB oversight to the Ascension Wisconsin IRB

5.1. The Ascension Wisconsin IRB performs a review and the transfer is not considered to be completed until the Ascension Wisconsin IRB has approved the transferred study.

5.2. The Ascension Wisconsin IRB determines whether any other engaged institutions have relied upon the transferring IRB for IRB oversight. If yes, the Ascension Wisconsin IRB works with those institutions to establish a new IRB Authorization Agreement between them.

5.3. The Investigator must request the transfer by submitting the Transfer Request form to Ascension Wisconsin Research Integrity and Protection.

5.3.1.The submission must also include applicable documents requested on the form, including:

- current approved protocol,
- approved consent form/ HIPAA authorization
- Recruitment material
- Drug or device information
- Research grant or funding application

5.4. The Investigator and all study staff must have an account in Mentor and complete all human subject training requirements prior to submission.

5.5. Research Integrity and Protection staff

- Work with the Investigator to obtain any additional information or documentation needed.
- Review the materials submitted and accept oversight.
- Determine if any modifications or any additional IRB or ancillary reviews are required before accepting oversight.

5.6. If staff has questions or concerns about the transfer, they may refer the submission to the IRB Chair or a designated reviewer.

5.7. Ascension Wisconsin Research Integrity and Protection will notify the Investigator of the oversight of decisions. Investigators will be responsible for notifying sponsors and/or other applicable parties.

6. Request to transfer IRB oversight from the Ascension Wisconsin IRB

6.1. In these cases the Receiving IRB will typically guide the transfer process.

6.2. If the Ascension Wisconsin will continue to be engaged in the research, the institutions will establish an IRB Authorization Agreement, as needed.

6.3. The Ascension Wisconsin IRB arranges to provide the other institution with a copy of any records it requests as part of the transfer, in the format requested by the other IRB.

6.4. When the transfer is completed, the Ascension Wisconsin IRB ensures that all transfer-related documentation has been placed in the IRB file. Appropriate staff is then notified so that the file can be closed following standard procedures.

REFERENCES

FDA Guidance: "Considerations When Transferring Clinical Investigation Oversight to Another IRB", 2014

RELATED MATERIAL

None

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/23/2017	New- Initial Integration Update	J. Blundon