SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Managing Concerns and Complaints Regarding Human Subject Research	Effective: 11/01/2017
		Approved: 10/25/2017
SOP ID		Last Revised: n/a
RIP-SOP-004		Expiration: n/a

PURPOSE

Ascension Wisconsin is committed to the protection of research participants and their families. Despite the best efforts of the Hospitals, Clinics, and the PI, concerns or complaints may arise regarding a participant's involvement in a research protocol. This SOP describes the manner in which such complaints are managed.

SCOPE

This SOP applies to all human subject research conducted within Ascension Wisconsin.

DEFINITIONS

Significant complaint/concern: A complaint or concern is considered significant it may adversely impact a participant's or a potential participant's safety, rights or welfare, or if it results in required change to the study protocol or consent form.

PROCESS

1. **Research Subject Resources**
   - **1.1.** Research participants and their families are encouraged to express their concerns, at any time, directly to the Principal Investigator (PI) or any other member of the research team.
   - **1.2.** They are also made aware that they can speak to Research Integrity and Protection (RI&P) staff to voice concerns or complaints to the research staff, investigator or the IRB office. Subjects are notified of this option in the informed consent document. Informed consent documents must include a statement describing that subjects may contact the Research Subject Advocate with any questions, concerns, or complaints regarding their rights as a research subject, along with a phone number.
   - **1.3.** All concerns and complaints are to be addressed in a timely and thorough manner.

2. **Reporting a Concern or a Complaint**
   - **2.1.** Complaints, concerns or questions may be raised by research subjects (past, present and potential), family members, designated spokespersons or anyone**.**
   - **2.2.** Complaints, concerns, or questions may be provided to the PI or study team, to RI&P by phone or in writing, or using the complaint line for any Ascension Wisconsin location.

3. **Responding to Participant Concerns or Complaints**
   - **3.1.** When the PI or study team receive a concerns or complaint:
     - **3.1.1.** The PI and study staff is obligated to make a good faith effort to promptly respond to, and to try to resolve, any study-related concern or complaint they receive or are aware of.

3.1.2. Most reported concerns and complaints are minor and routine, e.g., a subject complaint about late study payment. You do not need to report minor or routine concerns that can be resolved quickly to the IRB.

3.1.3. Any significant complaint or concern must be reported to the IRB as a study-related incident.

3.2. When Research Integrity and Protection receives a concern or complaint directly:

3.2.1. RI&P staff responds to concerns and complaints received and will attempt to substantiate the complaint in a timely manner.

3.2.1.1. If a complaint is received directly from a research participant/family member, RI&P staff obtain information from them and indicate that they will be contacted within seven or fewer working days with an update on the inquiry into the concern or complaint. If it takes longer than seven working days to resolve the concern or complaint, the research participant is to be updated on a weekly basis until the concern or complaint is resolved.

3.2.2. RI&P staff member will ascertain the details of the complaint and the course of action thus far. This may involve discussion with the PI, other members of the research team, and/or other health care providers, to gather additional information to assist with the validation and/or dismissal of the complaint.

3.2.3. Once all the information is received, the IRB will determine if any further action is necessary to resolve the concern/complaint.

3.2.3.1. Any minor concerns or complaints are resolved with the complainant informally, often referring the participant back to the study team.

3.2.3.2. A significant concern or complaint, must be investigated in a more formal manor; additional actions are dependent on the complaint.

3.2.3.3. Any validated complaints and their resolution are reported to Risk Management and members of the IRB in a timely manner.

3.2.4. Other Potential Actions Pertinent to Concerns and Complaints

3.2.4.1. If necessary, the research protocol may be temporarily suspended by the IRB Chair/IRB until the details regarding the concern or complaint are resolved.

3.2.4.2. If the concern or complaint involves possible scientific misconduct, it is to be referred to the Institutional Official or Research Integrity Officer.

3.2.4.3. If necessary, the event is to be reported to the Office of Human Research Protections in accordance with the Institution's Federal-Wide Assurance of Compliance with Department of Health and Human Services requirements.

REFERNCES

None

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