		SOP
Department	**Title**	**Dates**
Research Integrity and Protection	Observation of the Consenting Process	Effective: 10/25/17
		Approved: 10/13/17
Policy ID		Last Revised: n/a
REQM-SOP-105		Expiration: n/a

PURPOSE

This policy defines when the Research Education and Quality Management may be asked to observe the consenting process.

SCOPE

This policy applies to all human research studies approved by the Ascension WI IRB.

DEFINITIONS

NONE

PROCESS

1. Research Education and Quality Management (REQM) has the authority to observe the informed consent process of research approved by Ascension WI IRB to verify that the consent process is being conducted as approved and in accordance with applicable federal regulations, state laws, and local institutional policies and procedures

2. **Consent Observation Selection and Initiation**
   - **2.1.** Consent observation may be initiated through various mechanisms, including by the IRB, the Principal Investigator (PI) and/or Study Team, or by other leaders or departments, such as the Clinical Research Office or Institutional Official.
   - **2.2.** In situations where the IRB of other leader requests the observation, the Research Integrity and Protection Director will notify REQM.
   - **2.3.** REQM will contact the study team to initiate a schedule and communication plan. This plan will be specific to the study and the IRB request.

3. **Observation Procedure**
   - **3.1.** Verbal consent of the subject should be sought prior to the observation of the consent process by the third party.
   - **3.2.** Observation of the consenting process may include:
     - Real-time in-person observation of a consent discussion.
     - Review of documentation of previous consent procedures.
     - Discussions with subjects (by phone or in person) about a consent discussion after it occurred.
     - Discussion and review of consenting procedures with the study team members delegated to obtain informed consent.

3.3. REQM staff will prepare a report which will address any identified areas requiring guidance, improvement or clarifications at the time of the observation. The report will be reviewed by the Director of Research Integrity and Protections before being sent to the investigator and Coordinator (if applicable) and the requestor, when applicable.

3.4. If there are any findings that require follow up, they will be noted on the report and the PI and/or Coordinator are expected to respond to minor issues within 10 business days. REQM staff may grant an extension as appropriate. If no response is received the REQM staff will send a reminder. If there is no response to the reminder, REQM staff may inform the IRB office that there is an outstanding response and the IRB may hold processing future submissions until resolved with REQM.

3.5. Documentation of study start up meetings are maintained by REQM and is not shared with other groups or departments, such as the IRB or Corporate responsibility except for rare cases where the PI will be informed in advance.

3.5.1. In the event that observations include recommended reporting to the IRB, an email may be sent to IRB staff with the portion of the Final Report that identifies what reportable events and actions the study team will be submitting to the IRB for review, in order to allow IRB staff to provide appropriate guidance and follow up on the required report.

REFERNCES

45 CFR 46.109(e)
21CFR 56.109(f)

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/13/2017	New- Initial Integration Update	J. Blundon