		SOP
Department	**Title**	**Dates**
Research Integrity and Protection	Study Start Up Meetings	Effective: 10/25/17
		Approved: 10/13/17
Policy ID		Last Revised: n/a
REQM-SOP-102		Expiration: n/a

PURPOSE
This policy is intended to define a study start up meeting and identify eligible studies.

SCOPE
All open, Ascension IRB approved human research studies are eligible for a Study Start Up Meeting.

DEFINITION
Eligible study: All open, Ascension IRB approved studies.

PROCESS

1. A Study Start Up Meeting is a service offered by Research Education and Quality Management (REQM) to ensure investigators and coordinators understand the requirements of conducting a study and maintaining complete and accurate research files prior to initiating a new study.

2. Study start up meetings may be initiated by REQM staff following study submission to the IRB or IRB approval, the Principal Investigator (PI) and/or Study Coordinator.

3. Research Education and Quality Management Initiated Study Start Up Meeting
- **3.1.** REQM staff are notified via email when the Ascension IRB has approved a new study.
- **3.2.** If the PI and/or main study coordinator are new to conducting research at Ascension Wisconsin, the REQM staff sends the PI and Study Coordinator an email invitation to participate in a voluntary study start up meeting.
- **3.3.** Upon acceptance, a mutually agreeable time will be scheduled for the visit.

4. PI/Coordinator Initiated Study Start Up Meeting
- **4.1.** The PI/Coordinator may contact the REQM staff to request a Study Start Up Meeting.
- **4.2.** A mutually agreeable time will be scheduled for the visit.

5. Study Start Up Meeting Procedures
- **5.1.** Upon scheduling a study start up meeting, the REQM staff emails the PI and Coordinator a link to the REQM website which offers a Regulatory Binder template.
- **5.2.** REQM will clarify with the study team if they will generate the binder or if they would like REQM to generate the binder.
- **5.3.** The meeting may include, but is not limited to, discussion of the purpose of the Regulatory Binder and its contents, tools for study management, discussion of the documentation requirements for obtaining informed consent, and other templates available on the Research Education and Quality Management website. REQM can also address any specific questions that the PI and/or coordinator have.

5.4. If requested by the study team, REQM may attend research staff training meetings scheduled by the PI to assist in answering questions on topics such as best documentation practices or the informed consent processes.

5.5. REQM staff will prepare a report which will be reviewed by the Director of Research Integrity and Protections before being sent to the Investigator and Coordinator (if applicable). The report will address any identified areas requiring guidance, improvement or clarifications at the time of the Study Start Up Meeting.

5.6. 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.

5.7. 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.

5.8. In the event that observations include reporting to the IRB, an email may be sent to IRB staff with the portion of the Final Report that identifies what 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.

REVISION HISTORY

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