SOP

Department	Title	Dates
Research Integrity and Protection	Routine Reviews	Effective: 10/25/17
		Approved: 10/13/17
Policy ID		Last Revised: 3/26/2018
REQM-SOP-103		Expiration: n/a

PURPOSE

This policy is intended to define a Routine Review, the purpose, eligible studies and the review process.

SCOPE

All open protocols for human research studies, humanitarian use devices or expanded access protocols being conducted at Ascension Wisconsin, regardless of the IRB of record, are eligible for Routine Reviews by Research Education and Quality Management (REQM).

DEFINITION

Routine Reviews: Not-for-cause assessments of research practices performed with feedback provided regarding the conduct of the study to the PI and study team.

Eligible study: All open, Ascension IRB approved studies. Exceptions may be made to conduct a review of a closed study (i.e. a sponsor will be conducting an audit due to high enrolling site after the study has closed).

PROCESS

1. The purpose of a routine review include providing education and support to ensure good research practice; ensuring the rights, welfare, and safety of human subjects are properly protected in accordance with the Belmont Report and federal, state, and institutional requirements governing human subjects research; and assisting in preventing the occurrence of errors by ensuring research protocols are implemented as approved by the IRB. Additional reasons a routine review may be conducted include staff reorganization, upcoming external audit or sponsor monitoring visit.

2. Routine Review Selection and Initiation

2.1. Routine reviews may be initiated through various mechanisms, including by Research Education and Quality Management, the Principal Investigator(PI) and/or Study Team, or by other leaders or departments, such as the Clinical Research Office or Institutional Official.

2.1.1. REQM staff will determine eligible studies to be reviewed, with input from Director of Research Integrity and Protection as needed. Study selection may be based on risk level, the number of previous reviews of the study and/or PI or other factors driven by administrative or strategic goals.

2.2. Once a study has been identified, the PI and Coordinator (if applicable) will be informed by email that their protocol has been chosen for review and request enrollment status of the study.

2.3. A mutually acceptable time is scheduled for the Routine Review.

2.3.1. When the review is initiated by REQM, a review is scheduled only when there are subjects enrolled. If enrollment has not started yet, the review will be postponed and the coordinator will be contacted again in the future. In the event that the study team

would like a review conducted of the study even though enrollment has not begun, the review will be scheduled.

2.4. The PI will be copied on the email correspondence and/or Outlook appointment to ensure the PI is aware of the upcoming review.

3. Routine Review Procedures

3.1. During a Routine Review, REQM staff may use the Regulatory Review Checklist, ICD Tool and Subject File Tool to review documents including, but not limited to: regulatory files, informed consent documents, subject files, source documents and other study related documents.

3.2. The PI and/or Research Coordinator do not need to be present for the entire Routine Review. However, REQM staff may ask to meet with the investigator or Coordinator before (to discuss study practices). The PI or Research Coordinator should also be available (or to check in periodically) to answer any questions that may arise during the review. Prior to leaving the site, the PI and/or Coordinator may provide REQM with the information needed to resolve a finding.

3.3. A debriefing will be scheduled following the review to discuss the findings. The debriefing may occur either the same day, or a different day than the review, if needed to accommodate schedules and time to summarize the findings.

3.3.1. The debriefing will typically be conducted in person. If there is a research Coordinator, the coordinator is required to attend. The PI is highly encouraged to attend, but may delegate to the coordinator. For reviews in the Clinical Research Office, the Director may also be asked to attend.

3.3.2. In the rare event that a debriefing cannot be scheduled, the PI and coordinator will be allowed 5 business days to review and comment on a draft of the review report, described below, in order to provide feedback or clarification on findings.

3.4. REQM staff will prepare a report which will be reviewed by the Director of Research Integrity and Protection before sending to the PI, Coordinator (if applicable) and Director, Research Department (if applicable).

3.4.1. The report may address positive findings and will include identified areas needing improvement, including directions to promptly report any serious concerns to the IRB.

3.4.2. Findings are categorized as: resolved during review, no recommendations, recommendation to optimize research practice, minor issue identified (REQM Coordinator will correspond with study team until addressed), and promptly report to the IRB.

3.4.3. When the review is requested by another leader or department, the requestor will also be copied.

3.5. The PI and/or Coordinator are expected to respond to REQM minor issues within 10 business days; REQM staff may grant an extension as appropriate.

3.5.1. 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.

3.6. Documentation of the Routine Review is 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.

3.6.1. 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

OHRP Guidance, “Written IRB Procedures: OHRP Guidance” 2011

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/13/2017	New- Initial Integration Update	J. Blundon
02	3/26/2018	Clarified purpose and scope. Updated/clarified section 3 to more clearly outline the review and debrief process	J. Blundon