SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Virtual Reviews	Effective: 10/25/17
		Approved: 10/13/17
Policy ID		Last Revised: n/a
REQM-SOP-104		Expiration: n/a

PURPOSE

This policy is intended to define a Virtual Review, its purpose and eligible studies.

SCOPE

All open, Ascension IRB approved human research studies.

DEFINITIONS

Virtual Reviews: Not-for-cause assessments of research practices that are completed without visiting the site.

Eligible study: All open, Ascension IRB approved studies.

PROCESS

1. The purposes of a virtual 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 without physically visiting the site. Additional reasons of a virtual review may include staff reorganization, upcoming external audit or sponsor monitoring visit.

2. Virtual Routine Review Selection and Initiation

2.1. Virtual reviews may be initiated through various mechanisms, including by Research Education and Quality Management (REQM), 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 Protections 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 list of items needed from the study team will be sent to the PI and Coordinator with a date deadline.

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.

3. Virtual Review Procedures

3.1. During a Virtual Review, REQM staff populates a Self- Assessment Tool while reviewing the study in Mentor. The Self-Assessment Tool is forwarded to the PI for completion.

3.2. REQM may request study documents including, but is not limited to all signed informed consent documents, Site Delegation Log and Enrollment log.

3.3. The PI or Research Coordinator may be asked to answer any questions that may arise during the review via email or telephone.

3.4. REQM staff will prepare a report which will be reviewed by the Director of Research Integrity and Protections before sending the final to the investigator and Coordinator (if applicable). The report will address positive findings and identified areas needing improvement, including directions to promptly report any serious concerns to the IRB. Findings are categorized as: resolved at time of 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.

3.5. 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 Research Education and Quality Management staff will send a reminder. If there is no response to the reminder, Research Education and Quality Management 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 Virtual 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 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