		SOP
Department	**Title**	**Dates**
Research Integrity and Protection	For Cause Audits	Effective: 10/25/17
		Approved: 10/13/2017
Policy ID		Last Revised: n/a
REQM-SOP-106		Expiration: n/a

PURPOSE

This policy is intended to define a For-Cause Audit, its purpose and identify eligible studies.

SCOPE

All open, Ascension IRB approved human research studies are eligible for a For-Cause-Audit by Research Education and Quality Management (REQM).

DEFINITION

For Cause Audit: A For-Cause Audit is an in-depth examination of all components of a research study including, but not limited to all records and documents, observations of processes, and interviews with investigators, research staff members, and participants for the purpose of determining if the rights and welfare of participants are being upheld according to federal, regulatory, IRB and institutional requirements.

PROCESS

1. **Purposes**
   - **1.1** For-Cause audits are performed to promote the highest degree of research standards in the conduct of human subject research.
   - **1.2** Reasons for conducting a For-Cause audit includes; but are not limited to:
     - **1.2.1** Investigator has history of poor adherence to Ascension policies and procedures.
     - **1.2.2** Research Integrity and Protection receives an internal complaint or concern (i.e., from a subject or family member, Ascension associate, or other Ascension entity).
     - **1.2.3** Research Integrity and Protection receives an external complaint (i.e., from OHRP, the FDA, or a sponsor) of potential protocol violation or regulatory non-compliance.

2. **Requests to Conduct a For-Cause Audit**
   - **2.1** For-Cause audits are initiated at the request of Ascension IRB, the Director of Research Integrity and Protections, the Director of the Clinical Research Department, VP of Compliance, or Institutional Official to obtain or verify information necessary to ensure compliance with the regulations and institutional requirements and to inform decisions about the conduct of human subjects research and/or human subject protection.
   - **2.2** Ascension IRB, the Director of Research Integrity and Protections, the Director of the Clinical Research Department, VP of Compliance, or Institutional Official may request a for-cause audit. Justification for the evaluation shall be documented in writing and must include all of the relevant issues to support the need for the evaluation.
   - **2.3** The Investigator is contacted regarding the For-Cause evaluation (in writing) and a mutually acceptable time is negotiated. However, it may be necessary to schedule a For-Cause evaluation without first obtaining the formal agreement of an investigator (for example, where there is a suspected increased risk of harm to subjects or others).

2.4 The evaluation is conducted by Research Education and Quality Management.

2.5 REQM may request documents to assist in preparing for the evaluation (for example, the enrollment log or site delegation log).

3. Reporting of Findings

3.1 The REQM staff will prepare a summary which will be reviewed by the Director of Research Integrity and Protections before sending the final to the PI, Coordinator and Requesting Individual, if applicable. The summary will describe the observation, and will address positive findings and identified areas of improvement.

3.2 REQM staff may be asked to attend an IRB meeting to present the findings.

3.3 Documentation of the For-Cause Audit is maintained by REQM and will be shared with the IRB, Institutional Official or other leaders as appropriate, only in summary form, unless specifically requested.

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