



Department	Title	Dates
Research Integrity and Protection	Routine IRB Evaluations	Effective: 10/25/17
		Approved: 10/13/17
Policy ID		Last Revised: n/a
REQM-SOP-107		Expiration: n/a

PURPOSE

This policy is intended to define routine IRB evaluations and its purpose.

SCOPE

All open, Ascension IRB approved human research studies are eligible for routine IRB evaluations by Research Education and Quality Management (REQM).

DEFINITIONS

None

PROCESS

1. The objectives of IRB evaluation exercises are to determine adherence to the Belmont Report, federal regulations, state law, institutional policy, and IRB policy.
2. **Documents reviewed**
 - 2.1 Internal evaluations may include Review of IRB meeting minutes to ensure all elements outlined in IRB SOPs, IRB Records and Files, are included as appropriate.
 - 2.2 Routine REQM evaluations of IRB operations are conducted to review and assess the IRB files, database records, actions of the convened IRB, membership roster, and minutes.
 - 2.3 Review random selection of Exempt and Expedited Studies to measure the accuracy of category selection; use of checklists (staff and reviewers); accuracy and completeness of correspondence; actions are appropriately posted to agenda; check to ensure the electronic and paper file system is organized and maintained in a functional manner; check Continuing Reviews-Notice of Expiration to ensure prompt notification to the investigator of an expiration; and other evaluations as determined by Director of Research Integrity and Protection.
3. **Reporting of Findings**
 - 3.1 Outcomes of the IRB evaluations are used to address educational issues involving IRB Administrators and IRB Chair.
 - 3.2 IRB evaluation findings are provided to and discussed with the Director of Research Integrity and Protection at the conclusion of an evaluation exercise.

REVISION HISTORY

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