



Department	Title	Dates
Research Integrity and Protection	Consultants, Observers and Guests	Effective: 10/25/2017
SOP ID		Approved: 3/1/2017
IRB-SOP-502		Last Revised: n/a
		Expiration: n/a

PURPOSE

This SOP is intended to explain when and how the IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

SCOPE

This SOP applies to all IRBs established within Ascension Wisconsin and all staff or members who serve on the IRBs.

DEFINITIONS

Consultants: A consultant is an expert, such as an advisor, ad hoc reviewer, or others who may assist in the review of a complex research project.

PROCESS

1. Consultants

- 1.1.** During initial review RI&P staff or IRB members may determine that the current membership of the IRB does not include appropriate expertise to conduct an adequate study evaluation and may invite individuals with competence in special areas to assist in the review. This determination will be based on the topic of the protocol and the expertise of the voting members.
- 1.2.** Consultants may be sought throughout the review process as follows:
 - The IRB staff, in consultation with the IRB Chair, determines upon pre-review that a consultant is required.
 - Members of the IRB may request at any time during the review process to add a consultant to the review process.
 - IRB member reviewers may seek consultation during the review of a proposed research study by directly contacting colleagues for information related to a research study. Before obtaining advice from a consultant in this manner, the IRB committee member should ensure that the colleague does not have a conflict of interest with the research study.
- 1.3.** Consultants may be either internal or external to the institution. Consultants may be identified in a variety of ways including from past IRB members, through collegial relationships, or by contacting the department chair or division chief (or their designee) of the area from which the research is being submitted.
- 1.4.** Consultants will be provided with protocol information prior to the meeting, which may include the IRB submission forms, protocol and consent document as well as any attachments (investigator brochures, multicenter protocols, etc.).

- 1.5. Consultants may attend an IRB meeting or provide written comments to be taken into consideration by the Committee during its review. They may also be asked to provide specific input such as answer written questions of the IRB panel or discuss the outstanding issue with the Chair.
- 1.6. During an IRB meeting, consultants are not counted for the purposes of establishing quorum and are not considered voting members. Additionally, any consultant or expert will not be present for the final discussion or vote on the proposal.
- 1.7. Consultants must comply with Conflict of Interest policies for members. The IRB staff member who communicates with the consultant will establish Conflict of Interest status. If a conflict is disclosed, another consultant will be sought.
- 1.8. Use of consultants will be documented in the IRB protocol file and minutes.

2. Observers and Guests

- 2.1. Observers and guests may attend the IRB meetings at the discretion of the Chair(s). Whenever possible, IRB staff should be notified ahead of time about observer or guest attendance.
- 2.2. Guests and observers are individuals with a particular interest in the IRB and do not attend regularly.
- 2.3. Neither guests nor observers count as part of the quorum and are not permitted to observe the final discussion and vote for any protocol in which they may have a potential or actual interest.
- 2.4. All observers and guests are advised that the deliberations of the IRB are confidential.

REFERENCES

None

RELATED MATERIAL

Ascension Wisconsin Policy: Human Subject Research

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	4/11/2017	New- Initial Integration Update	J. Blundon