Use of Consultants by the Institutional Review Board (IRB) Guideline - Arizona, Florida, Rochester

Guidelines are recommendations, rather than rigid rules. Guidelines can be modified using professional judgment and may be adapted to many different situations.

Scope

Applies to Mayo Clinic Human Research Protection Program and research for which Mayo Clinic IRB is the IRB of Record when the IRB utilizes an internal or external <u>Consultants</u> for their expertise in a specific area.

Purpose

To provide guidance on obtaining consultation when expertise is needed beyond or in addition to the existing expertise on the IRB.

Guideline

Circumstances

The IRB may seek an ad hoc <u>Consultant</u> when expertise is needed to assist in the reviews that require expertise beyond or in addition to that available on the IRB. Such expertise may include scientific and scholarly expertise and/or knowledge about and experience working with certain topics or populations. Consultants may be used for all aspects of IRB review, including, but not limited to, initial review, modifications, reportable events, and continuing review.

Selection

A recommendation to engage a <u>Consultant</u> may be made to the corresponding IRB Chair or the IRB Medical Director by any IRB reviewer or an IRB operations supervisor, manager, or administrator. The IRB Chair or IRB Medical Director will select the <u>Consultant</u> based on:

- <u>Consultants</u> internal to Mayo Clinic may be identified through communication with the relevant Department Chair, or by IRB member or IRB administrative personnel knowledge of relevant local expertise.
- If necessary, <u>Consultants</u> external to Mayo Clinic with nationally prominent relevant expertise may be sought.
- No compensation is provided to Consultants.
- <u>Consultants</u> to the IRB may not have a conflict of interest in the application to be reviewed, as defined in the Mayo Clinic IRB Policy, <u>Management of IRB Member and Consultant Conflict of</u> <u>Interest</u>

Participation

A <u>Consultant</u> to the IRB may participate, either in person or using conferencing technologies, in the convened meeting during which the application is reviewed, for the purpose of presenting his/her review and answering the IRB's questions. Alternately, the <u>Consultant</u> may provide a written review that will be made available to the IRB members participating in the specific meeting.

<u>Consultants</u> may be given access to all documents relevant to the specific project under review, may participate in the IRB's deliberations and make recommendations on the project. However, <u>Consultants</u> may not vote with the members of the IRB and a consultant's presence or absence will not be used in establishing a quorum. Refer to the Mayo Clinic IRB Policy, <u>Conduct of Convened IRB Meetings</u>.

Guideline Notes

N/A

Related Documents

Conduct of Convened IRB Meetings

Management of IRB Member and Consultant Conflict of Interest

Definitions

Consultant: A scientist or non-scientist from within or external to Mayo Clinic who has special expertise, to act at the request of the IRB as an ad hoc reviewer of a research project application.

References

N/A

Owner

Tammy S. Neseth, M.A. on behalf of Office for Human Research Protection

Contact

Michelle K. Daiss, Heidi M. Hanf

Revision History

| Date | Synopsis of Change |
|------|--|
| | Scheduled review. Transferred to standardized template. Updated Owner and Contact. Minor revisions. |

| | Scheduled review - Updated to new template, no other changes due to AAHRPP accreditation cycle |
|------------|--|
| 03/01/2016 | Scheduled review - added "Revision History" to end of document |

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