Use of Consultants by the IRB Guidelines

Scope
Mayo Clinic Human Research Protection Program
Research for which Mayo Clinic IRB is the IRB of Record

Purpose
The purpose of this document is to describe how the Mayo Clinic IRB obtains consultation when expertise is needed beyond or in addition to that available on the IRB.

Guideline

Circumstances
The IRB may seek an ad hoc consultant 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 consultant may be made to the corresponding IRB Chair or the IRB Medical Director by any IRB reviewer or an IRB operations coordinator, manager, or administrator. The IRB Chair or IRB Medical Director will select the consultant, considering the following:

- Consultants 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, consultants external to Mayo Clinic with nationally prominent relevant expertise may be sought.
- No compensation is provided to consultants.
- Consultants to the IRB may not have a conflict of interest in the application to be reviewed, as defined in the Mayo Clinic IRB Policy, Management of IRB Member and Consultant Conflicts of Interest

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

Consultants 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, consultants may not vote with the members of the IRB and a consultant’s presence or absence will not be used in establishing a quorum (see the Mayo Clinic IRB Policy, Conduct of Convened IRB Meetings.)
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

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Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Synopsis of Change</th>
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<tr>
<td>January 15, 2018</td>
<td>Scheduled review - Updated to new template, no other changes due to AAHRPP accreditation cycle</td>
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<tr>
<td>March 1, 2016</td>
<td>Scheduled review - added &quot;Revision History&quot; to end of document</td>
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