Choosing Determinations for New Studies, Modifications, and Renewals
Objectives

- Review the IRB Standard Operating Procedure for Meeting Deliberations and Determinations
- Describe Determination Options and the Applicability of Each
- Relate Determinations to Criteria of Approval
Checklists, Be Sure To:

1. Compare the study to the criteria of the checklist
2. Check each appropriate box on the checklist
3. Write justifications where specified
4. Upload Your Completed Checklist to Your Reviewer Comments in IRBNet
And if you forgot to upload your checklist:

Please be sure to sign and date the completed checklist at the full committee meeting.
Your Placemat:
A Guide to In-Committee Deliberations and Determinations
International Research

The reviewer has materials necessary about the local research context through:

- Written materials such as (1) previous consultations;
- (2) information from the Department of State website; or
- (3) information from the OHRP Compilation of Human Research Standards; and/or
- Discussions with or written material from appropriate consultants with expertise in the local context where the research is being conducted.

The research appears to be acceptable in terms of institutional commitments, regulations, applicable law and standards of professional conduct and practice.

One of the following must apply:

- Approval will be/has been obtained from a local ethics committee; and/or
- Approval will be/has been obtained from a local authority

The reviewer has obtained necessary information about the local research context:

1. The types of subject populations likely to be involved;
2. Applicable law;
3. Local culture and norms related to the research, the research procedures, subject matter being researched, and informed consent (if applicable);
4. Method for protection of privacy of subjects;
5. Method for maintenance of confidentiality of data;
6. Language(s) understood by prospective subjects and methods for effectively communicating with them;
7. Method for minimizing the possibility of coercion or undue influence in seeking consent; and
8. Safeguards to protect the rights and welfare of vulnerable subjects.

The information was obtained by:

- Personal knowledge of the local research context on the part of one or more IRB members;
- Participation (either physically or through conference) by one or more appropriate consultants with personal knowledge of the local context in convened meetings of the IRB;
- Prior written review of the proposed research by one or more appropriate consultants in conjunction with participation (either physically or through audiovisual or telephone conference) by the consultant(s) in convened meetings of the IRB, when such participation is deemed warranted either by the consultant(s) or by any member of the IRB

One of the following must apply:

- Approval will be/has been obtained from a local ethics committee; and/or
- Approval will be/has been obtained from a local authority
KEEP CALM AND DRINK COFFEE