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Ethics Committees

Anant Bhan, MBBS, MHSc
Ethical Social and Cultural Program for the Grand Challenges in Global Health Initiative
Nancy E. Kass, ScD
The Johns Hopkins Berman Institute of Bioethics

Objectives of Session

- Understand the role and responsibilities of the ECs in the protection of the welfare of human research subjects

- Understand the basic operations and functions of ECs

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Section A: What an EC Is and How It Functions

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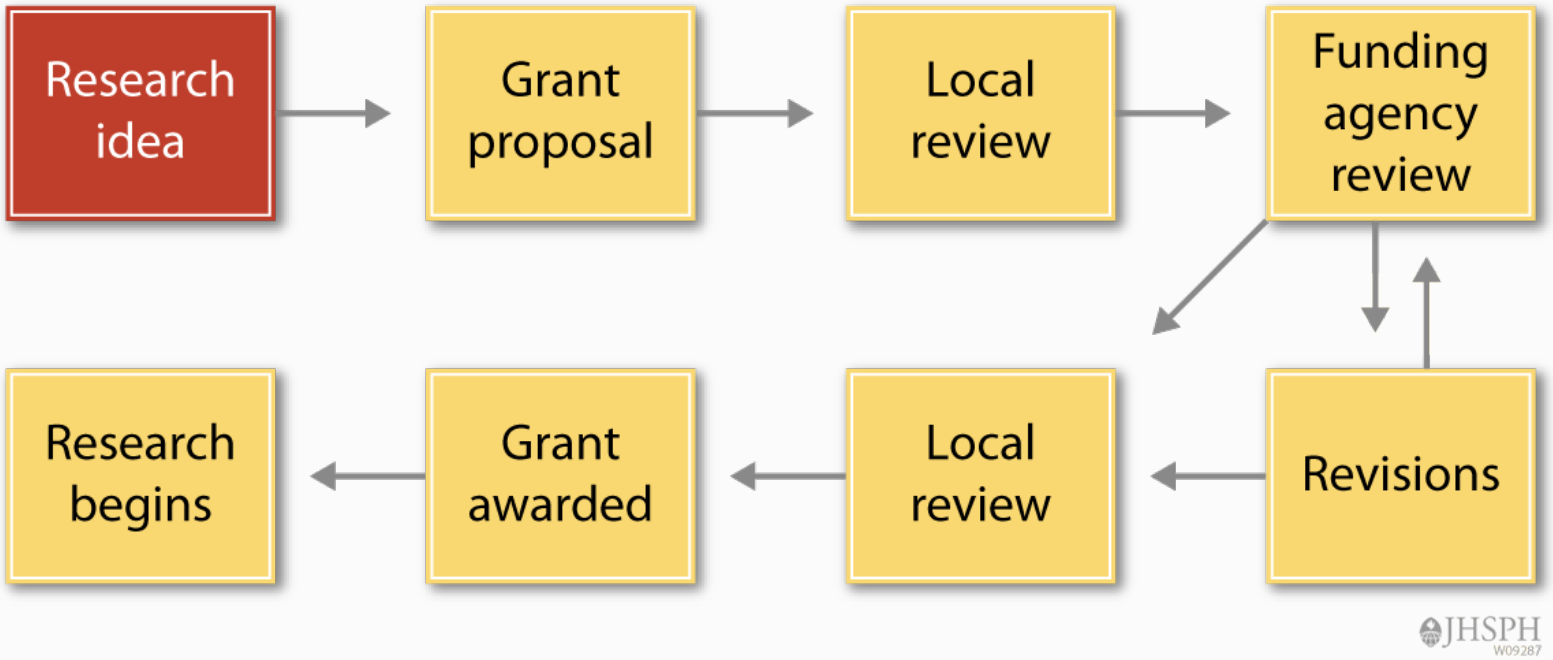
Life of Research Project



Definition: Ethics Committee

- A committee appointed to consider ethical issues and dedicated to protecting the rights and well-being of research participants

Nomenclature

- Ethics review board (ERB)
- Research ethics board (REB)
- Research ethics committee (REC)
- Institutional review board (IRB)
- Institutional ethics committee (IEC)

Role of the EC—NCESSRH Guidelines

- Functions of the EC
  - Protection: To contribute to the dignity, rights, safety, and well-being of all groups and persons related to the concerned project activity, this would include participants in the research, community at large, researchers, research community, and institution
  - Advice: Useful resource for commenting on project
  - Education: Of project staff
  - Analysis and documentation: For self-learning and educating others

Structure of EC

- Composition
  - Multidisciplinary and multisectorial in composition
  - Number of persons: 5/7–12/15

Members of EC

- Chair
- One to two basic medical scientists
- One to two clinicians from various institutes
- One legal expert or retired judge
- One social scientist/representative of NG voluntary agency
- One philosopher/ethicist/theologian
- One lay person
- Member secretary
- If required, subject experts could be invited to offer views

Specific Members of ECs

- Chair should preferably be from outside the institution and not head of the same institution to maintain the independence of the committee

- Member secretary from same institution should conduct the business of the committee

Functioning of ECs

- Described in terms of the following:
  - Review procedures
  - Decision-making processes
  - Documentation requirements

Review Procedures

- Scientific evaluation should be completed before ethical evaluation
- Evaluate possible risks to the subjects with proper justification
- Expected benefits

Review Procedures

- Adequacy of documentation for ensuring privacy, confidentiality and justice issues: application, budget, supporting documents (including consent form), etc.
- The ethical review should be done through formal meetings and should not resort to decisions through email or phone
- Decisions are preferably arrived at by consensus

Steps towards the EC Meeting

1. Prefixed dates for routine EC meetings

2. Submissions made by researchers in keeping with the requirements of the EC's SOP

3. Finalizing primary and secondary reviewers

4. The proposals circulated to members giving sufficient time for review

Steps towards the EC Meeting

5. The members undertake the review
6. The meeting of the EC
7. Discussions at the EC
8. Decisions made
9. The process and decisions are documented
10. These decisions and the reasons are communicated to the researchers

Preparatory Phase: Steps 1–4

- Step 1. Prefixed dates
  - Need to be finalized in advance
  - This helps researchers develop, finalize the materials
  - Plan in advance

- Step 2. Submissions to the EC
  - Knowledge of the dates facilitates timely submissions

Preparatory Phase: Steps 1–4

- Step 3. Primary and secondary reviewers
  - The secretariat of the ERB sorts through the proposals, allocates primary and secondary reviewers for the proposals that need full review

- Step 4. Sending of proposals
  - Proposals are mailed to all members

The Review Phase: Steps 5–9

- Step 5. The review
  - The members review the proposal keeping in mind the subjects (vulnerability, etc.), the process (consent, requirements for privacy and confidentiality, etc.), the study requirements (risks/benefits, etc.)
  - Seeks and obtains clarifications if necessary

The Review Phase: Steps 5–9

- Step 6. The EC meeting
  - Presided over by the chair
  - The members have done their homework!
  - Attend meeting and engage in discussion
  - If further clarifications needed, ask for the PI to be present
  - Discuss and discuss and discuss

The Review Phase: Steps 5–9

- Step 7. The discussions
  - The various members raise concerns regarding aspects of proposal
  - Many of the issues are clarified by within-group discussions
  - Usually the guidance from the ICMR guidelines and the various government regulations are referred to already by specific members when there are contentious issues
  - In case these are not adequate, the members also use other guidelines and use scholarly journals for additional support for decisions

The Review Phase: Steps 5–9

- Step 8. The decision
  - Usually all concerns are adjusted into the decision by way of recommendations to be taken into account before giving clearance
  - In case the requirements are trivial, the member secretary is authorized to obtain clarifications and give clearance
  - In case additional information is needed or the clarifications need further review, a sub-committee may be appointed or resubmission recommended

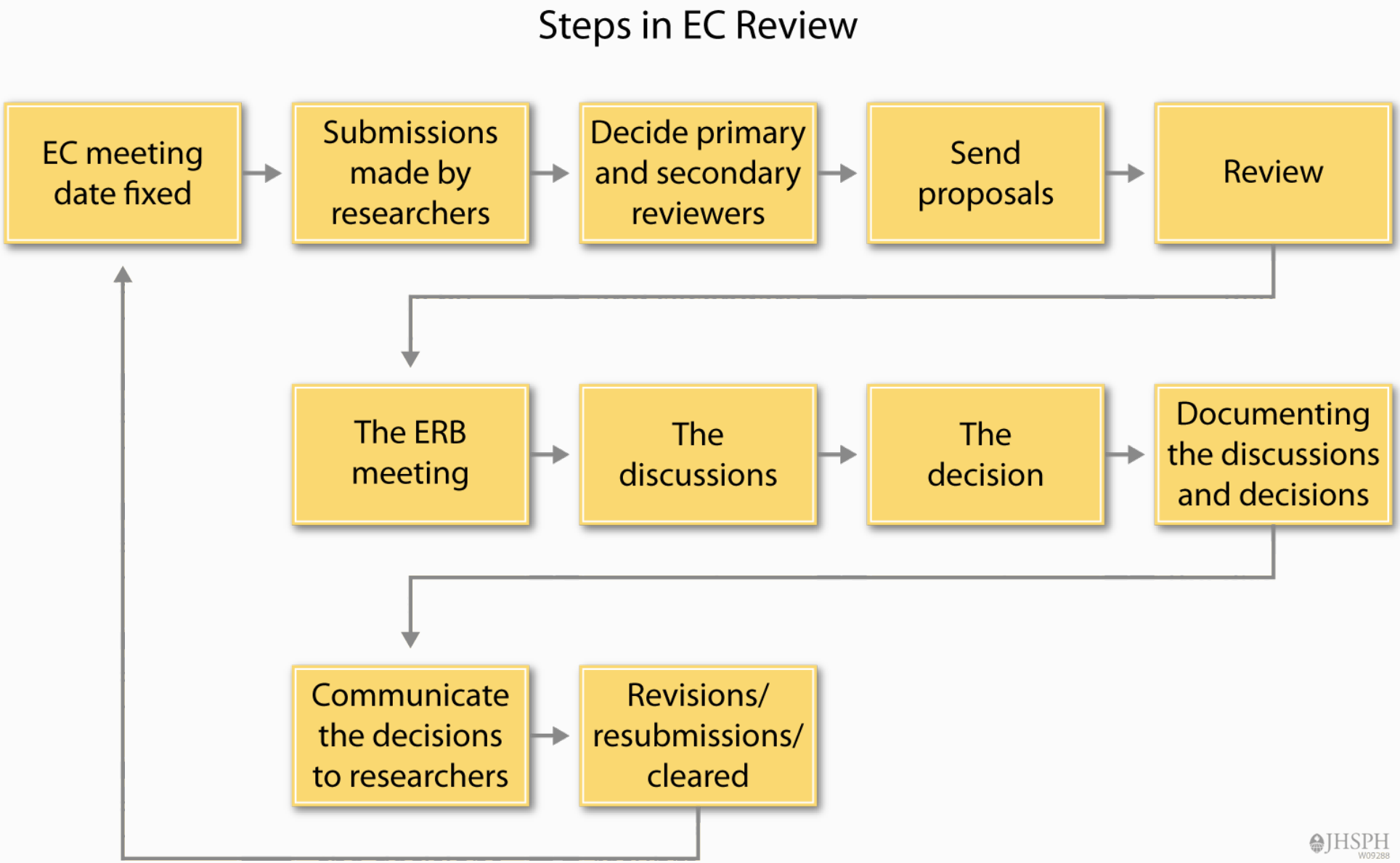
The Review Phase: Steps 5–9

- Step 8. Documenting the decisions
  - The member secretary keeps track of the discussions and decisions
  - Compiles the minutes and has them sent to all members present for corrections if any
  - Once these are returned, s/he prepares the minutes for approval by chair

The Review Phase: Steps 5–9

- Step 9. The communication with the researchers
  - The MS communicates these decisions to the researchers and also advises them on what is necessary in case of any recommendations that call for changes, usually within two weeks of the meeting

Steps in EC Review



Decision-Making Process—ICMR Guidelines

- Decision making
  - EC can reverse its decision on study after receiving information that will adversely affect risk-benefit ratio
  - Discontinuation should be ordered if EC finds that goals of trial have already been achieved midway or unequivocal results are obtained

Decision-Making Process—ICMR Guidelines

- The EC should be cognisant of …
  - Any amendment to the protocol from the originally approved protocol with proper justification
  - Serious and unexpected adverse events and remedial steps taken to tackle them
  - Any new information that may influence conduct of the study

Decision-Making Process

- If necessary the PI may be invited to present the protocol or offer clarifications
- Representatives of interest groups can be invited during deliberations to offer their viewpoint
- Subject experts' views can be invited, but they should not form a part of the decision-making process. Their opinions must be recorded.

The Decision Making

- Step 10. The decision
  - Outright approval (At most, only very minor changes are suggested. The application contained all necessary information.)
  - Approval with modifications (there is enough information to judge the study, but clarification or changes are needed)
  - Resubmit with more information (there is not enough information to judge the application appropriately
  - Outright disapproval (there is no way the researcher can ethically do study)