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Section C: Decision Making and Related Issues, DSMB

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Decision Making

- Any member with conflict of interest should not take part
- Only ethics committee members should take part
- Only members who participate in the review should participate in the decision

Decision Making

- There should be a predefined method for arriving at a decision
 - By consensus
 - By vote
- It is recommended that decisions be arrived at through consensus where possible
- When a consensus appears unlikely, it is recommended that the EC vote

Decision Making

- Decision should be communicated within two weeks of the meeting
- In the case of a negative decision, clearly state reason(s) for the negative decision

EC Decision Matrix

Beneficence

- Risk/benefit analysis
- Experimental design
- Qualifications of PI

Justice

- Subject selection
- Inclusion/exclusion
- Recruitment

Respect for persons

- Informed consent
- Surrogate consent
- Assent
- Privacy & confidentiality
- Protection of subjects (especially vulnerable populations)

Adapted by CTLT from J. Cooper, Albany Medical Center.

Appointment

- Authority by which appointed
- Membership requirements
- Terms of reference/SOPs
- Conditions of appointment

An EC Should Demonstrate ...

- Competence
- Efficiency
- Independence (from political, institutional, professional, and market influences)
- Consistency

Review Procedures—Interim Review

- How and when?
- Each EC to decide for itself, the procedure and mechanism
- Why?
- To re-examine a proposal
- To check if there is any valid scientific or ethical reason to suspend or terminate a study
- Expedited review

Data Safety Monitoring Board

- Different from an EC
- Plays a complementary role to an EC
- An independent group of experts in the relevant field and reviews the data collected in the trial at regular intervals to ensure the safety of the participants
- A DSMB also ensures that the study data is being properly collected, analyzed, and reported

- Role important, especially in double blind trials where data blinded to participants, researchers, and funders
- DSMB has access to unblinded data so that it can review risk-benefit on ongoing basis and take action if needed
- Meets regularly during the trial, making recommendations to researchers
- Created by the funder usually
- Recent examples—trial DSMBs stopped HIV vaccine trials globally for futility/harm and MC trials because benefit shown much earlier during the trial

Human Guinea Pigs

- If clinical trial participants are the guinea pigs, then the EC and DSMB are guardians of the cage.

Summary

- What an EC is
- Roles and responsibilities
- Decision making and review process
- Distinguished from DSMB

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