JOHNS HOPKINS
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Section B: Roles and Responsibilities, Requirements of EC

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Documentation Requirements

- Recordkeeping requirements
  - Meetings must be minuted and approved and signed by chair
  - Strict confidentiality
  - All documentation, including final reports of the study, microfilms, CDs, and video recordings, need to be kept safe for a fixed amount of time (depending on EC SOP)

Responsibilities of ERB Members

1. To provide competent review of all ethical aspects of the project

2. Undertake review free from bias and influence

3. Provide advice to the researchers on all aspects of welfare and safety of research participants

Review of All Ethical Aspects of the Project

1. To provide competent review of all ethical aspects of the project
   - Undergo appropriate training to enhance competence
   - To maintain confidentiality of documents obtained and discussions during the review process
   - To allocate time for reviewing the proposals

Review Free from Bias and Influence

2. Undertake review free from bias and influence
   - Need to put on record various interests, financial or otherwise, to avoid conflict of interest
   - Reflexivity about the nature of engagement with protocols
   - Non-judgmental and unbiased decision making

Provide Advice on Participant Welfare and Safety

3. Provide advice to the researchers on all aspects of welfare and safety of research participants
   - Need to build capacity of researchers
   - Provide ongoing review
   - Monitor the taking of consent
   - Ensure that the guidance from the EC is actually followed
   - Keep oneself informed of the research process and re-review when ever necessary

Expedited Research

- Minimal risk studies
  - "No more than risks encountered in every day life"
- Minor changes to approved studies
- Do not need full EC review—chair decides about subsection which will look at it
- Inform EC of decisions

Role and Responsibilities

- Consent authority
  - Waiver of informed consent
    1. Research involves no more than minimal risk
    2. Will not adversely effect welfare
    3. Research not practical without waiver
    4. Subjects will be provided with information

Role and Responsibilities

- Review responsibilities
  - Continuing
    - Annual updates
    - Amendments to study
    - Adverse event reports

Review

- All properly submitted applications should be reviewed in a timely fashion and according to an established review procedure

Elements of the Review

- Scientific design and conduct of the study
- Recruitment of research participants
- Care and protection of research participants
- Protection of research participant confidentiality
- Informed consent process
- Community considerations

Scientific Design and Conduct of the Study

- The appropriateness of …
  - Study design
  - Statistical methodology
  - Sample size calculation

- The justification of …
  - Risk-benefit ratio
  - Use of control arms

Scientific Design and Conduct of the Study (cont.)

- Criteria for prematurely withdrawing research participants
- Criteria for suspending or terminating the research as a whole
- The manner in which the results of the research will be reported and published

Recruitment of Research Participants

- The characteristics of the population
  - Gender
  - Age
  - Literacy
  - Culture
  - Economic status
  - Ethnicity

- The means of …
  - Initial contact and recruitment
  - Conveying information

- Inclusion and exclusion criteria for research participants

Care and Protection of Research Participants

- The suitability of the investigator(s)
  - Qualifications and experience

- Any plans to withdraw or withhold standard therapies and the justification

- The medical care to be provided to research participants during and after the course of the research

Care and Protection of Research Participants

- The adequacy of medical supervision
- Steps in case of voluntary withdrawal
- The arrangements for informing family doctor
- Description of any plans for continued care

Care and Protection of Research Participants

- The rewards and compensations for research participants
  - Money
  - Services
  - Gifts
- The provisions for compensation/treatment
- The insurance and indemnity arrangements

Protection of Research Participant Confidentiality

- A description of the persons who will have access to personal data and biological samples

- The measures taken to ensure the confidentiality and security of personal information

Informed Consent Process

- A full description of the process including the identification of those responsible for obtaining it
- The adequacy, completeness, understandability of written and oral information
- Clear justification for the intention to include in research individuals who cannot consent

Community Considerations

- The impact and relevance of the research on the local community
- The steps taken to consult with the concerned communities during the course of designing and course of research
- A description of the availability and affordability and accessibility of the successful study product to the community