JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Section B

Components of IC

Information Required in IC Form (ICMR Guidelines)

1. Nature and purpose of study stating it as research
2. Duration of participation with number of participants
3. Procedures to be followed
4. Investigations, if any, to be performed
5. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk

Information Required in IC Form (ICMR Guidelines)

6. Benefits to participant, community, or medical profession as may be applicable

7. Policy on compensation (in case of injuries related to research)

8. Availability of medical treatment for such injuries or risk management

9. Alternative treatments if available

10. Steps taken for ensuring privacy and confidentiality

Information Required in IC Form (ICMR Guidelines)

11. No loss of benefits on withdrawal

12. Benefit sharing in the event of commercialization

13. Contact details of PI, or local PI/Co-PI in multicenter studies, for asking more information related to the research or in case of injury

14. Contact details of chairperson of the ethics committee for appeal against violation of rights

Information Required in IC Form (ICMR Guidelines)

15. Voluntary participation

16. If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines

17. Storage period of biological samples and related data with choice offered to participant regarding future use of sample, refusal for storage, and receipt of its results

Other Information

- Compensation/payment provided for participation
- Insurance coverage (if relevant)
- Implications for participant: time, cost, number of visits, procedures like blood draws, etc.
- No statement permissible in form which asks for waiver of any legal rights or releasing investigator/sponsor/institution from liability for negligence
- Circumstances for termination of subject's participation by investigator
- Also necessary to give time to participant to decide

IC and ICMR Guidelines

- Signature or thumb impression
- If nature of study sensitive, then verbal consent documented by unrelated witness
- Audio-visual methods can be used with the permission of ethics committee

IC and ICMR Guidelines

- A copy of consent form to be provided to participant
- Should mention withdrawal from study possible at any time
- Risks/benefits mentioned
- Assurances around respecting privacy/confidentiality

Waiver of IC

- At the discretion of the ethics committee
- In minimal-risk studies or emergency situations or special cases
- When privacy and confidentiality concerns do not arise (e.g., anonymized biological samples) or review of publicly available information
- In some cases deception may be permitted, but usually disclosure has to happen later

Reason for Documenting Consent

- Regulatory/legal requirements
- Serves as a study record
- Helps keep track of study participants and when they entered/left
- It's necessary, however, to remember that the process is paramount, not the document or the documentation

The Declaration of Helsinki and Informed Consent

- Subjects must be …
  - Volunteers
  - Informed participants

- Consent must be obtained, preferably in writing

- If a subject is in a dependent relationship with the physician, consent must be obtained by an independent physician

The Belmont Report and Informed Consent

- *The Belmont Report* identified three elements of the process
  1. Information
  2. Comprehension
  3. Voluntariness

The Belmont Report and IC

- Information
  - All information provided
  - Conditions under which information provided is also important (rapid/disorganized manner?)

- Comprehension
  - Adapt presentation of information to subject's capacities
  - Investigators must ascertain comprehension
  - Special provisions—immaturity, mental disability

- Voluntariness
  - There must be no coercion or undue influence