National Policy for Institutional Review Boards (IRBs)

Adapted from Office for Human Research Protection

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Prepared By

Dr. Faiz Bashir (HRI NIH)
Dr. Nighat Murad (HRI NIH)
Ms. Sualeha Siddique Shekhani (CBEC SIUT)
Ms. Tayyaba Rahat
Mr. Mazhar Iqbal

Reviewed by

National Bioethics Committee Members

Approved by

Chairperson NBC

Definitions

1. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

2. **Human subject** means an individual (alive or dead) about whom an investigator (whether professional or student) conducting research obtains
   (i) Data through intervention or interaction with the individual, or
   (ii) Identifiable private information

   For the purpose of this study, at some point there will be an intervention or interaction with subjects for the collection of biospecimens or data (including health or clinical data, surveys, focus groups or observation of behavior).
   Or identifiable private information or identifiable biospecimens will be obtained, used, studied, analyzed, or generated for the purpose of this study.

   Intervention includes both physical procedures by which data are gathered (for example, vein puncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
   Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
   Private information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

3. **IRB** means an institutional review board established in accord with and for the purposes expressed in this policy.
4. **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
5. **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

6. **Non-human subject research** involves only unidentifiable or coded information or biological specimens which cannot be linked to an individual.

Policy for Protection of Human Research Subjects by IRBs in Pakistan

a) This policy applies to all research (involving all health-related human subjects research) conducted in any institution or on people of Pakistan in any form in Pakistan. This includes research conducted by federal or provincial institutions, Clinical Research Organizations, consultancy firms, donors, industry or by independent researchers. It also includes research conducted, supported, or otherwise subject to regulation by the Government of Pakistan.

   i. Research that is done in Pakistan must be reviewed and approved by the relevant IRB and National Bioethics Committee for Research (NBC-R).
   ii. Research that is conducted or supported by a federal entity including those in Azad Jammu and Kashmir, and Gilgit Baltistan.

b) Compliance with this policy requires compliance with pertinent federal and provincial policies/ regulations which provide additional protections for human subjects.

c) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

d) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. Hence, this policy does not affect any foreign laws or regulations which may otherwise be applicable.

e) Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity (for example, Investigational New Drugs and device requirements administered by the Drug Regulator Authority of Pakistan). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the departments or agency's broader responsibility to regulate certain types of activities whether research or non-researching nature (SAAL, Newsletter etc).

Assuring compliance with this policy research conducted or supported by NBC-R.

a) Each institution involved in the research needs to establish its own independent IRB registered by NBC.
b) The information of the IRB needs to be publicly available on the institute's website.
c) Each institution shall provide written assurance that it will comply with the requirements set forth in this policy.
   i. Institutions will conduct or support research only if the institution has certified that the research has been reviewed and approved by an, and will be subject to continuing review by the IRB.

ii. A statement of that may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself.
iii. A list of IRB members identified by name and roles in IRB; earned degrees;
iv. Written procedures which the IRB will follow like SOPs
v. Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials responsible for reporting to, and the department (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance and (ii) any suspension or termination of IRB approval.

d) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution
e) The head of institution will evaluate and certify all application and materials submitted to NBC for registration in accordance with this policy.
f) On the basis of this evaluation, the Head of Institution may approve or disapprove the assurance, or enter into negotiations to develop an approvable one.

IRB Membership:

a) Each IRB should consist of a reasonable number of members who collectively have the education, training, skills and experience to review and evaluate the type of research proposals the committee is most likely to receive.
b) The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
c) In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.
d) If an IRB regularly reviews research that involves vulnerable category of subjects, such as children, orphans, displaced persons, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
e) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of all sexes, so long as no selection is made to the IRB on the basis of sex. No IRB may consist entirely of members of one profession.
f) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
g) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
h) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting/ competing interest, except to provide information requested by the IRB.

i) An IRB may, in its discretion; invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals, also known as co-opted members, may not vote with the IRB.

j) An IRB will ensure that all members are provided sufficient protections for their fair decision-making

IRB Functions and Operations:

Each IRB shall:

a) Follow written procedures and, to the extent required by the policy
    i. Except when an expedited review procedure is used to review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in non-scientific areas.
b) In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.
c) Hold meetings at least once every quarter and document minutes of each meeting.
d) In case of any grievance within the IRB, the NBC may be approached for guidance.

IRB review of research:

a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities.
b) An IRB shall require that information given to subjects as part of informed consent.
    i. The IRB must require that information, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
    ii. An IRB shall require documentation of informed consent or may waive documentation in accordance.
c) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity.
d) If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in writing.
e) An IRB shall conduct continuing review of research covered at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.
f) An IRB shall direct all international collaborative research or international funded research for NBC approval

Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

a) The Secretariat, NBC-R, has established, and published a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication by NBC-R.
b) An IRB may use the expedited review procedure to review either or both of the following:
    i. research involving no more than minimal risk,

ii. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

c) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.
d) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.
e) IRB may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

Criteria for IRB approval of research:

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits.
3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative. Informed consent will be appropriately documented.
5. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects like by Data Safety and Monitoring Boards in case of clinical trials.
6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, orphans, displaced persons, sexual and gender minorities, patients tied for their treatments like programs, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
8. Adverse event reporting systems are mentioned and corrective and preventive actions are clearly mentioned with anticipated risks.
9. Sufficient evidence of insurance if applicable (incase of clinical trials especially)

Review by institution:

Research been approved by an IRB of another participating institutions and MOUs/ LOUs are provided.

Suspension or termination of IRB approval of research:

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the NBC/ DRAP/ IRB's requirements or that has been associated with unexpected serious harm to subjects.
Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Institutional Head, as well as the NBC.

IRB Records:

a) An institution, or when appropriate an IRB shall prepare and maintain adequate documentation of IRB activities, including the following:
   1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of any adverse events to subjects.
   2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.
   3. Records of continuing review activities.
   4. Copies of all correspondence between the IRB and the investigators.
   5. A list of IRB members in the same detail
   6. Declaration of competing/Conflict of Interest of Members
   7. Written procedures for the IRB in the same detail.
   8. Statements of significant new findings provided to subjects.

b) The records shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in reasonable manner.

Evaluation and disposition of applications and proposals for research:

a) The IRB will evaluate all applications and proposals involving human subjects. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
b) On the basis of this evaluation, the IRB may approve or disapprove the application or advise to develop a revised version that's acceptable in the context.

Early termination: Evaluation of applications and proposals:

a) The IRB may require for any project be terminated or suspended when the IRB finds an institution has materially failed to comply with the terms of this policy.