Standard Operating Procedures (SOP) for National Ethics Committee for Health Research (NECHR) in Cambodia

Objective:

The objective of this SOP is to contribute to the effective functioning of the NECHR in Cambodia so that a quality and consistent ethical review mechanism for health and biomedical research is put in place.

Scope

The SOP applies to all procedures related to the ethical review of protocols submitted to the NECHR and its operation and management. It covers the following sections:

1. Structure and Membership of NECHR
2. Review Requirements and Procedures
3. Board Meetings
4. Monitoring
5. Management of Files and Records
6. Audit and Inspection
7. Revision and Guideline Preparation

1. Structure and Membership of NECHR

1.1. Role of NECHR

NECHR will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual or potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The NECHR will ensure that all the cardinal principles of research ethics viz. Respect for rights (Autonomy), Beneficence (Non-malfeasance) and Justice are taken care of in research protocols. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the studies as well as monitor

the research throughout the study until and after completion by examining the annual reports and final reports. The committee will also examine whether all regulatory requirements and laws are complied with or not.

For the time being, NECHR is the only entrance for all research proposals to be reviewed. NECHR can seek advice from relevant departments or institutions. Later on, NECHR will consider setting up Institutional Review Boards (IRB) of reasonable field and number. NECHR will ensure that all registered IRB function well according to the NECHR guidelines.

1.2. Membership of NECHR

The membership of NECHR should include Epidemiologist(s), Sociologist(s), Layer(s), Statistician(s), Clinician(s), Microbiologist(s),Pharmacist(s). They should be proposed by the minister of Health and approved by Prime Minister based on their competencies and integrity, and could be drawn from the Ministry of Health relevant departments and institutes. Experts from WHO and other organizations concerned should be part of the committee as quality or technical advisors. The chairperson will nominate the Secretariat team.

NECHR should have:

i) A Chairperson
ii) Two Deputy Chairpersons
iii) Secretariat team
iv) 15 members from different Departments, Specialties, fields etc.

1.3. Authority under which NECHR is constituted:

NECHR is proposed by Minister of Health and nominated by Prime Minister

1.4. Membership requirements:

a. The members are proposed by the Ministry of Health

The members are drawn from different departments and specialties to give a multi-sectorial, multi-dimensional structure. One third on NECHR members need to be proposed and renewed every five

years. The Chairperson will propose the new committee members to the Minister of Health.
Gender should be considered. Membership of NECHR consist of at least

-Medical science
-Non medical science
-Outside the institution

b. Chairperson and members are appointed by Prime Minister with the mandate of 5 years.
c. A NECHR member can be replaced in the event of death or long-term assignments outside the country, absence for 5 consecutive meeting without any valid reason or for any misconduct deemed unfit for a member.
d. A member can tender resignation from the committee with proper reasons, which should be acceptable to Chairperson and approved by Prime Minister.
e. All members should maintain absolute confidentiality of all discussions during the meeting.
f. All NECHR members should have training on human subject protection
g. Independent consultants can be invited in order to evaluate risk and benefit of specific research

1.5. Functions of Officers and Members

- Chairperson
  - chairs meetings
  - submits annual report to the Ministry of Health,
  - appoints the secretariat team, independent consultants and other needed staff.
  - assigns primary reviewers with appropriate expertise to review the protocol.
- Vice Chairperson – substitutes for the Chairperson and performs other tasks assigned by the Chairperson
- Secretary – heads the Secretariat and takes care of NECHR administration

1.5.1. Members

- Participate in meetings

- Review, discuss and consider research proposals and vote accordingly
- Monitor serious adverse event reports and recommend appropriate action
- Review the progress reports and monitor ongoing studies
- Evaluate final reports and outcomes
- Maintain confidentiality of the documents and deliberations
- Sign a confidentiality and conflict of interest agreement at the beginning of their appointment.
- Declare any conflict of interest during discussion and voting on protocols
- Participate in continuing education activities in biomedical ethics and biomedical research

1.5.2. Secretariat

- Organizing an effective tracking procedures for protocols
- Preparing, maintaining and distributing study files
- Organizing NECHR meetings
- Preparing meeting agenda and minutes
- Maintaining documentation and archives
- Communicating the NECHR members and applicants
- Arranging training for personnel and NECHR members
- Organizing the preparation, review, revision and distribution of SOPs
- Providing the necessary administrative support for NECHR
- Providing updates on relevant and contemporary issues
- Receiving and distributing protocol for review based on expertise of individual members.
- Reviewing protocol when appointed by the Chairperson but have no right to vote
- Declaring any conflict of interest
- Participating in continuing education activities in biomedical ethics and health research ethics.

All members and officers of the NECHR and independent consultants sign a confidentiality and conflict of interest agreement.

1.6. Updating NECHR members

a. All relevant new guidelines to be brought to the attention of the members.
b. Members should attend initial training and be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and to be aware of the latest developments in this area.
c. NECHR members who have attended research ethics training can provide training to other interested members.

1.7. Independent consultants

NECHR may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the NECHR.

Independent Consultants:

- ☐ Appointed by the Chairperson of the NECHR.
- ☐ Providing assessment or advising on specific protocols
- ☐ Relevant professional qualifications required
- ☐ Willing to disclose and publicize full name, profession, and affiliation, financial accountability
- ☐ Willing to sign Confidentiality and Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

1.8. Quorum requirements:

The minimum of 50% +1 members are required to compose a quorum. All decisions should be taken up in meetings and not by circulation of project proposals.

1. 9. Offices

The National Institute of Public Health (NIPH) is the permanent office of the Committee.

2. Review Requirements and Procedures

2.1. Applications Procedures:

a. All proposals are to be submitted in the prescribed application form, the details of which are given under the Documentation Section.
b. The proposal shall be in Khmer and English or French
c. All relevant documents should enclose the application form
d. 20 copies of the proposal along with the application in prescribed format to be submitted duly forwarded by the Director of the Institution.
e. Electronic file of submitted proposal and related documents are required
f. The date of meeting will be communicated to the researcher to be present, if necessary to offer clarifications.
g. The decision will be communicated in writing. If revision is to be made, the revised document in 20 copies to be submitted before the next meeting.

2.2. Documents required for application:

For a thorough and complete review, all research proposals are to be submitted with the following documents:

1. Name of the applicant with designation
2. Name of the Institute/ Hospital /Field area where research will be conducted.
3. Approval of the Director of the Institution
4. Summary of the protocol in Khmer and English.
5. Protocol of the proposed research
6. Ethical issues in the study and plans to address these issues.
7. Questionnaires, follow up card, etc.

8. Patient information sheet and informed consent form in local language.
9. For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other countries, if available.
10. Statement describing compensation for study subjects for participation and/or study related injuries.
11. Curriculum vitae of all the investigators with relevant publications in last five years.
12. Any regulatory clearances required.
13. Source of funding and financial requirements for the report. Budget details are required.
14. An agreement to report any serious side effects or adverse drug reactions to NECHR.
15. Statement of conflicts of interest, if any.
16. Any other information relevant to the study
17. The review fee of an equivalent amount of US$ 400 for research proposals except research done by students without sponsors. In case the proposal needs to be revised, the next review will not be charged.

2.3. Types of Review

The Secretariat determines what type of review is required for each protocol received

2.3.1. Expedited Review
Applicable to

- Non significant risk protocols
- Protocols that are non confidential
  - Not likely to harm/to offend
- Involve non invasive/routine procedures (finger stick collection of blood samples but not use of x-rays or microwaves)
- Protocols that use previously collected data/specimens
- Minor revision of previously approved protocol
- Non procedural items (names of personnel, etc.)

2.3.2. Expedited Review Procedures

- The Chairperson nominates 2 or more NECHR members to review the protocol (previous reviewers if resubmission)
- The reviewers review complete protocol.
    - Circulate protocol for comments or telephone discussion or meeting to arrive at a consensus.
    - In the absence of consensus or if NECHR member expresses concern, protocol is referred for full review.
- The reviewers forward the decision to secretariat that notifies the full board.
- Communicate the decision to the investigators.

2.3.3. Full Board Review Procedures:

a. Chairperson assigns 2 or 3 primary reviewers with appropriate expertise to review the protocol.

Note: Two NECHR members and one secretariat member can review, fill out the assessment form and report to the full board during the review process

b. The primary reviewers use the assessment form to review the protocol.
c. The primary reviewers report their assessment during the meeting.
d. The meeting of the NECHR will be held once in 2 months and the date will be the last Friday afternoon of each designated month. However, if needed, meetings can be held earlier as decided by the Chairperson.
e. All proposals for review will be sent to members at least 2 weeks in advance.
f. Independent consultants/Experts will be invited to offer their opinion on specific research proposals.
g. Decisions will be taken by majority vote
h. Researchers will be invited to offer clarifications if need be.
i. The decisions will be recorded and Chairperson's approval taken in writing.

2.3.4. Elements of Review

2.3.4.1. Primary reviewers review protocol and related documents:

a. Scientific design and conduct of the study.

b. Approval of appropriate scientific review committees.
c. Examination of predictable risks/harms.
d. Examination of potential benefits.
e. Procedure for selection of subjects: Exclusion/ Inclusion criteria.
f. Management of research related injuries, side effects, ADRs (Adverse Drug Reaction).
g. Provision for monitoring safety
h. Involvement of vulnerable participants
i. Justification for placebo in control arm, if any.
j. Availability of products after the study, if applicable.
k. Protection of privacy and confidentiality.
l. Involvement of the community, wherever necessary.
m. Plans for data analysis and reporting
n. Adherence to all regulatory requirements
o. Ownership of the research data and results (Ref. Article 12 &13 of the Ethical Guidelines for Health Research Involving Human Subjects, MoH)

Quotes:
"Article 12: Study reports and data
Any research carried out in the Kingdom of Cambodia, whether locally or externally sponsored or administered, should have a copy of the research report deposited at the National Institute of Public Health and their data belonging to the nationals.
Article 13: Release of the study results
Study results should be published without any interference from the sponsoring or administrative authorities".

2.3.4.2. Primary reviewers examine qualifications of investigators and staff

a. Related training and experience
b. Current license
c. Track record
d. Current involvement
e. Disclosure of conflict of interest
f. Role of team members (physician adviser)
g. Adequate number of staff

2.3.4.4. Primary reviewers evaluate study sites

a. Adequate staff support (Ex. Physician or staff on call)
b. Number of current projects
c. Adequate physical facilities
d. Protection of privacy and confidentiality of data

2.3.4.5. Primary reviewers review the following in community research

a. Community involvement and impact
b. Community participation
c. Local involvement
d. Local capability building
e. Benefit to local communities
f. Availability of study results

2.3.4.6. Primary reviewers review the following elements in the consent form

a. Statement that study involves research
b. Explains purposes of research
c. Expected duration of subject participation
d. Description of procedures to be followed
e. Identification of experimental procedures
f. Description of foreseeable risks and discomforts
g. Description of benefits to the subject and others
h. Disclosure of alternative procedures
i. Description of how extent of confidentiality or records will be maintained
j. Compensation and medical treatment for possible injury
k. New findings in the course of the research may affect subject's decision to continue
l. Approximate number of subjects
m. Study treatments and possible random assignments
n. Additional information required by local laws
o. Contact person for questions and research related injury
p. Voluntary participation and no penalty or loss of benefit for non participation
q. Statement that particular procedure may involve unforeseeable risk
r. Additional costs to subjects

s. Consequence of early withdrawal

2.3.5. Reviewing Protocol Amendments

a. Secretariat receives documents and checks completeness of documents
b. Secretariat forwards documents to reviewers
c. Reviewers check if recommendations are followed.
d. Reviewers report to the board and recommends appropriate action.
e. Board takes action on the amendments.

2.4. Follow up procedures

Principal investigators are responsible to

a. Submit regular progress reports as specified in the approval document.
b. Submit final report at the end of study.
c. Report any serious side effects, adverse drug reactions and the interventions undertaken to be intimated.
d. Report protocol deviation, if any, to be informed with adequate justifications.
e. Report any new information related to the study should be communicated.
f. Notify the NECHR about premature termination of study with reasons and summary of the studies done so far.

3. Board Meetings

Types of Board Meetings

Regular Board Meetings
Adhoc Meetings

3.1. Regular Board Meetings

3.1.1. Preparation before a board meeting

- Secretariat reviews all study applications for completeness and determines appropriate channel for each protocol.
- Primary reviewers are determined by the Chairperson and protocols and forms sent.
- Secretariat prepares agenda and schedules Board meeting.

- Chairperson reviews and approves agenda

3.1.2. Agenda during a board meeting:

- Chairperson determines the existence of a quorum.
- Secretariat reports on the minutes of previous meeting and presents agenda for discussion.
- Chairperson reminds members of rules being followed (confidentiality and conflicts of interest rules) and proceeds according to the agenda.
- Reviewers present summary of their assessment about the protocol and present evaluation followed by discussion with other members.
- Investigators may be allowed during the meeting discussion and may be asked to answer questions.
- Board takes action on
    - New protocols
    - Protocol amendments
    - Serious adverse events
    - Continuing review reports
    - Final report for the study
- Chairperson discusses other matters.
- Chairperson ends the meeting.

3.1.3. Activities after the board meeting

- Minutes of the meeting are prepared and contain the following:
    - Secretariat team prepares the minutes and write down the following:
        - Place and date of meeting
        - Attendance
        - Chair for the meeting
        - Agenda items
        - Quorum determination
        - Voting results including reasons for disapproval and abstention
        - Frequency of continuing review required
        - Other matters taken up during the meeting
- Secretary checks correctness of minutes and has it approved by the Chairperson.

- Secretariat files the minutes.
- Secretariat sends minutes to Board members.
- Secretariat sends meeting results to persons concerned.

3.1.3 Decision-making

a. Members will discuss the various issues before arriving at a decision.
b. Decisions will be made only in meetings where quorum is complete.
c. Only members can make the decision. The expert consultants will only offer their opinions.
d. Decision may be to approve, disapprove or modify the proposals. Specific suggestions should be given for modifications.
e. All approval decisions should indicate frequency of continuing review depending on how risks involved in the protocol. However, all investigators are required to submit a progress report at least once a year.
f. Modified proposals may be reviewed by an interim review through identified members.
g. Negative decisions should always be substantiated by appropriate reasons.
h. Secretariat team member can provide clarification if needed.

3.1.4 Voting Procedures

a. Only board members without conflict of interest are allowed to vote on protocol approval.
b. All observers and board members with conflict of interest leave the room during the discussion and the voting.
c. There should be a determination of quorum before voting takes place.
d. A board member makes a motion to recommend action on a protocol and is seconded by another member.
e. A motion is carried out based on majority vote.

3.1.5 Communicating the decision

The Secretariat prepares a letter to communicate the decision with

  - Listing of each approved document
    - protocol
    - patient information sheet
    - consent form
    - advertisement, etc.
  - Frequency of continuing review
  - Other obligations of the investigator
- Stamps approval and expiration date on every page of the consent form
- Obtains signature of Chairperson
- Sends action letter to investigator
- Keep record

3.2 Adhoc Meetings

- Scheduled outside of a regular meeting
- Scheduled to review or approve
  - Any safety or life threatening issue
  - New studies
  - Additional investigators
  - Continuing review
  - Protocol amendments
  - Other study activities that requiring full board review
- The Chairperson is responsible to call for a meeting.
- A resource person may be invited to provide required information (Ex. A physician to give information about medical care given to patients.)
- Quorum is required and maintained during voting.

4. Monitoring Protocol Implementation

The NECHR takes action and maintains records for any of the following deviation/non compliance

- Investigators/institutes who do not follow procedures in approved protocols
- Fail to comply with national/ international guidelines for the conduct of human research
- Fail to respond to NECHR requests

General Procedures

- Secretariat includes details of non compliance of investigators in the NECHR agenda/meeting

- Secretariat maintains a file of non compliant investigators
- Board may decide to do any of the following:
    - Suspend or withdraw approval of current study
    - Refuse subsequent application for non compliance
- Secretariat notifies relevant parties about the board decision:
    - Investigator/ institute
    - Relevant national authorities
    - Sponsor
- Secretariat keeps records and follows up.

NECHR monitors protocol implementation through the following means:

- Requiring continuing review reports
- Requiring final report for the study
- Receiving patient feedback and answering queries from participants
- Analyzing Serious Adverse Events (SAE) reports received
- Making site monitoring visits

4.1. Continuing Review Report Procedures

4.1.1. Secretariat

a. Determines due date for continuing review report for each protocol
b. Notifies investigator and sends the continuing reviewed form to be filled up.
c. Receives and manages continuing review package
d. Notifies NECHR members who will review the report
e. Includes report in the next meeting agenda

4.1.2. Investigator submits continuing review report to NECHR with the following information:

a. Number of subjects needed as defined in the protocol
b. Number of subjects enrolled during the period
c. Number of subjects who continue to be in the study
d. Number of subjects who completed the study
e. Number of subjects withdrawn

f. Any changes/amendments *(protocol/informed consent, investigator, funding, etc)*
g. Any Serious Averse Events (SAE)
h. Any new information
i. Any complaint from subjects
j. Any community concerns
k. Date of report and signature of investigator

4.1.3. Primary reviewers review the report and recommend action.

4.2. Final Study Report Procedures

4.2.1. Secretariat

a. Determines due date for final study report for each approved protocol
b. Notifies the investigator and sends the final report form to be filled up.
c. Receives and manages the final study report
d. Notifies NECHR members who will review the report
e. Includes report in the next meeting agenda

After the meeting, the Secretariat

- Notifies the investigator of the decision and sends an acknowledgement letter
- Accepts and files the final study report
- Notes in the minutes of the meeting
- Considers the study as “closed”
- Archives the entire protocol with final study report

4.2.2. Primary reviewers review the report and recommend action.

4.3. Patient Feedback and Queries from Participants
Procedures

- The Chairperson designates a staff member to receive and take action on participant inquiries or requests.

- Secretariat receives the request, notes information needed, records request and refers request to NECHR Chairperson

- Chairperson takes any of the following action:
    - Provides advice
    - Informs other members
    - Follows up at the next meeting
    - Delegates task to investigate
- Secretariat records information
- Secretariat reports to the board about action taken or outcomes.
- Secretariat keeps record and stores file.

4.4. Addressing Serious Adverse Events (SAE)

4.4.1. Definition
Serious Adverse Event is an event characterized by any of the following:

- Death
- Life-threatening condition
- Hospitalization (initial/prolonged)
- Disability
- Congenital anomaly
- Requires intervention to prevent permanent impairment or damage

Unexpected Adverse Drug Reaction (ADR) is an adverse reaction the nature or severity of which is not consistent with the investigator's brochure.

4.4.2. Serious Adverse Event Procedures

a. The Serious Adverse Event is reported by investigators or sponsors within 7 days after the event.
b. The Serious Adverse Event report form contains the following information

- Subject identification
- Onset / date of event
- Signs and symptoms
- Diagnosis
- Severity
- Relationship to the study

- Progression of Serious Adverse Event
- Modification in the protocol

c. The NECHR
- Makes sure the investigators are aware of the policies and procedures of reporting the Serious Adverse Event
- Reviews and addresses the Serious Adverse Event
- Takes action under appropriate circumstances

d. The Secretariat or NECHR member screens and assesses the report
e. During full board meeting, a determination is made if the Serious Adverse Event:
- Definitely, probably, possibly related
- Unexpected
- Resulting in changing of the protocol/informed consent

f. NECHR discusses the Serious Adverse Event and similar experiences or advisories
g. NECHR may call for:
- Continue the study
- Request an amendment
- Request further information
- Withdraw approval of the study

h. The Secretariat sends a letter to notify the Investigator of the NECHR decision/action

4.5. Site Monitoring Visits
The NECHR Chairperson assigns a member / Secretariat members, or a qualified agent to perform on-site visit.
A site visit is done as a result of any of the following:
- Reports of remarkable Serious Adverse Event
- Non-compliance or suspicious behavior
- Complaints from participants
- Investigator has never been approved
- New study sites
- Number of studies at the sites
- Frequently fail to submit documents as requirement

Site Visit Procedures

Before a site visit

- NECHR notifies the investigator and coordinates a time for a visit
- Secretariat makes appropriate arrangement
- Review files for the study and site
- Copy some parts of the files for comparison with the site files

During a site visit

- Get a checklist of site visit
- Visiting process
    - Review informed consent
    - Randomly review the subject files
    - Observe consent process, if possible
    - Observe facilities Review NECHR file
    - Collect views of the participant
    - Debrief/comments
    - Get immediate feedback

After the site visit

NECHR representative will:

- Write a report within 2 weeks
- Prepare a copy for full board review
- Send a copy of report to the site
- Place the report in the correct files
- Schedule the presentation in the meeting agenda
- Present the results of on-site visit to the full board

4.6. Managing Study Termination

- Study termination – when subject enrollment and follow up are discontinued before the scheduled end of the study
- Basis for protocol termination:
    - When safety or benefit of study participants is doubtful or at risk
    - Recommended by:
        - Local authorities
        - Scientists

4.6.1 Study Termination Procedures

- Receive recommendation for study termination
- Inform investigator to submit a protocol termination package that includes
    - Brief summary of protocol, results and accrual data
- Chairperson reviews reasons, results and data and calls for a meeting to approve termination.
- Secretariat completes documentation of termination.
- Notify the investigator.
- Store protocol documents

5. Management of Study Files and Records

5.1. Organize active study files

- Gather, classify and combine all related documents
- Check the content of active files
    - Original applications and any updates
    - Approval letters and correspondence
    - Approved documents
    - Investigator's brochure
- Assign identifiers
- Keep in a secure file cabinet
- Store the study files for at least 5 years after the study closure

5.2. Keep and maintain the following files

The Secretariat maintains the following files:

- SOP file
- Membership file
- Protocol file to contain
    - Index
    - Protocol (all versions)
    - Amendment report
    - Annual report
    - Serious Adverse Event report
    - Approval letters
    - End of study reports
    - Miscellaneous related items
- Minutes and agenda file
- Communication records
- National and international guidelines

5.3. Archiving documents

Secretariat

- Review the final report
- Move files from the active study filing area to archives
- Verify all documents in an organized manner
- Attach an archive number to the file

5.4. Retrieving documents

The Secretariat

- Ensures and maintains confidentiality
- Retrieves upon request signed by NECHR chairperson or appointed person
- Signs and dates the request in the log of request
- Retrieves
- Returns the file back to its place
- Records, signs and dates when the document is returned

6. Audit

The NECHR will prepare itself for audit by international organizations interested in its operations.

The audit has to be approved by the Chairperson.

6.1. Preparing for audit

- Use a checklist to review records, documents and items required by the audit.
- Focus on studies with problems.
- Organize and label records.
- Reserve a meeting room with necessary facilities.
- Review SOPs and ensure compliance
- Inform Board members/ staff who have to attend the meetings.

6.2. During an audit

- Meet with auditors
- Provide information and documents needed.
- Take note of comments and recommendations of auditors.

6.3. After the meeting

- Review comments and recommendations

- Prepare a report to be approved by the Chairperson who calls for correction.
- Allocate time for correction and improvement.
- Do an internal follow up audit.
- Evaluate the outcome.
- Keep records of proceedings.

7.Revision of SOPs and Preparing Guidelines

7.1. Revising SOPs

The Chairperson

- Assigns an SOP team
- Reviews and approves SOPs
- Signs and dates approved SOPs

The Secretariat

- Coordinates writing, reviewing, distributing and amending SOPs
- Maintains on file all current SOPs and list of SOPs
- Maintains an up to date distribution list
- Distributes SOPs with receipts from all users
- Ensures all EC members and staff have access to SOP
- Ensures that EC members and staff work according to current version of SOPs

NECHR members and staff

- Sign and date SOPs they receive.
- Maintain a file of all SOPs received.
- Return all out of date SOPs to the Secretariat
- Any member may request for SOP revision for various reasons (inconsistency, update, etc.)

7.2. Guideline Preparation

Guideline – any suggestion, rule or regulation intended for a specific practice (Example – Guidelines for genetic research or HIV/AIDS research)

- Purpose – for consistency of action, transparency and good order
- Responsibility – Secretariat or designated person(s) prepare the guidelines
- The Chairperson approves the guidelines

The secretariat distributes copies and informs the members.

Appendices:

1. confidentiality/conflict of interest agreement form
2. A. Application form for INITIAL Review
2. B. Contents of submitted packages
2. C. Assessment form (in Computer)
2. D. NECHR Decision form
2. E. Review of Resubmitted Protocol
2. F. Information Sheet and Consent form
3. A. NECHR Agenda form
4.A. Continuing Review Application form
4. B. Final Study Report form
4.C. Deviation/non-compliance/violation record
4.D. Participant request record form
4.E. Study termination form
4. F. SAE report
4.G. Checklist of Monitoring Visit
5.A. Document request form
5.B. Log of requests for copies of NECHR's documents
5. C. Database Requirements
7.A. Document History
7. B. Log of SOP recipients

Glossary of terms and definition (page 5-7)

1. Confidentiality / Conflict of Interest Agreement Form

In recognition of the fact, that I…..*member's name, and his/her affiliation*…….herein referred to as the "Undersigned", has been appointed as a member of the NECHR has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the NECHR is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an NECHR member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the NECHR must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The undersigned, as a member of the NECHR is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the NECHR. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in the NECHR and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the NECHR that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the NECRH.

The Undersigned will immediately disclose to the Chairperson of the NECHR any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that NECHR member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the NECHR member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.
When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the NECHR review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated

Agreement) will be kept on file in the custody of the NECHR. A copy will be given to you for your records.

In the course of my activities as a member of the NECHR, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I, ……., have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Undersigned Signature Date

_____ _____

Director of the …*INSTITUTE*… Date

2. A. APPLICATION FORM for INITIAL REVIEW

Protocol Title:	
Protocol number:	Total Participants to be included:

STUDY TYPE: (Mark "✓ " whichever apply to the study)

☐ Survey ☐ Social ☐ Medical ☐ Community based ☐ Individual based

☐ Screening ☐ Observational ☐ Epidemiology ☐ Intervention study

☐ Clinical Trial : ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV
☐ Genetic Study ☐ Retrospective ☐ Prospective ☐ Others……..

STUDY POPULATION: ☐ Healthy ☐ Patient ☐ Vulnerable groups

CHARACTERISTICS of PARTICIPANTS PARTICIPATED :

Age Range: ☐ 0 -17 yrs ☐ 18 - 44 yrs ☐ 45 - 65 yrs ☐ ≥ 66 yrs
Pediatric ☐ None ☐ < 1 yr ☐ 1-3 yrs ☐ 4 -14 yrs
Impaired ☐ None ☐ Physically ☐ Cognitively ☐ Mentally

REQUESTED EXCLUSION OF PARTICIPANTS:

☐ None ☐ Male ☐ Female ☐ Children ☐ Other (specify)_____)

SPECIAL RESOURCE REQUIREMENTS (check all that apply):

☐ Intensive Care ☐ Isolation unit ☐ Surgery
☐ Pediatric Intensive Care ☐ Transfusion ☐ CAT scan
☐ Gene therapy ☐ Controlled substances (Narcotics/Psychotropics)
☐ Prosthetics ☐ Gynecological services ☐ Others, specify……..
☐ Organ transplantation, specify…… ……..

IONIZING RADIATION USE (X-rays, radioisotopes, etc):

☐ None ☐ Medically indicated only

INVESTIGATIONAL NEW DRUG (IND) / DEVICE (IDE):

☐ None ☐ IND ☐ IDE
FDA No.:…… FDA No:……_____
Name:…… Name:……_____
Sponsor:…… Sponsor:……_____
Holder:…… Holder:……..

PROCEDURE USE: ☐ Invasive ☐ Non-invasive

MULTI-SITE COLLABORATION: ☐ YES ☐ NO

FINANCIAL DISCLOSURE: ☐ YES ☐ NO

INSTITUTE RESEARCH CONTACT
Name:……..…….....…. _____
Address:……..…. _____
Telephone:…… _____
Fax:…… _____
E-mail:…….. _____

2. B. Contents of a Submitted Package

Protocol Number:……..

☐ **Initial Review Submitted Package**

- ❑ Protocol Summary Sheet or Memorandum
- ❑ Original Initial Review Application Form
- ❑ Protocol and Protocol-Related Documents
  - ☐ information for subjects
  - ☐ informed consent form
  - ☐ case report forms (CRF)
  - ☐ study budget
  - ☐ investigator's brochure
  - ☐ others……

☐ *Resubmission for Re-review Submitted Package*

- ❑ Resubmission or "Correction" Memorandum
- ❑ Revised Protocol Summary Sheet (if submitted initially)
- ❑ Original Initial Review Application Form
- ❑ Protocol and Protocol-Related Documents
  - ☐ information for subjects
  - ☐ informed consent form
  - ☐ case report forms (CRF)
  - ☐ study budget
  - ☐ investigator's brochure
  - ☐ others……

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the document or the software package used to prepare the documents.

☐ **Protocol Amendment Submitted Package**

- ❑ Request for Amendment Memorandum
- ❑ Original Amendment Submission Form
- ❑ Protocol and Protocol-Related Documents

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the software package used to prepare the document.

☐ **Annual Continuing Review Package**

- ❑ Request for Annual Continuing Review Memorandum
- ❑ Original Continuing Review Application Form
- ❑ Current Informed Consent Document (last approved by NECHR)

☐ **Protocol Termination Package**

- ❑ Request for Termination Memorandum
- ❑ Original Continuing Review Application Form (Termination Submissions are contained on this form).

2. C. Assessment Form

GUIDE FOR ETHICS EVALUATION
OF RESEARCH WITH HUMAN PARTICIPANTS

TITLE: _____

PROPONENT: _____
_____
_____

1. Is research methodology clear?	____Yes ____No
2. Does the protocol present adequate informational background as to results of previous studies prior to human experimentation?	____Yes ____No
3. Is inclusion and exclusion criteria appropriate?	____Yes ____No
4. Does the research involve vulnerable participants?	____Yes ____No
5. Is there recruitment of participant voluntary and non-coercive?	____Yes ____No
6. Is there sufficient number of participants?	____Yes ____No
7. Is there a placebo arm?	____Yes ____No
8. Are qualification and experience of researchers appropriate?	____Yes ____No
9. Are facilitate and infrastructure of participating sites?	____Yes ____No
10. Community research • Is there community consultation? • Are local researchers involved? • Does it contribute to development capacity in research and treatment? • Is there benefit to local community? • Is there provision to share research result?	 ____Yes ____No ____Yes ____No ____Yes ____No ____Yes ____No ____Yes ____No
11. Will blood/tissue sample be sent abroad?	____Yes ____No
12. Does the protocol include an adequate process for assuring that consent is voluntary?	____Yes ____No
13. Does the protocol adequately address the risk/benefit balance? • What are the risks? Are they minimal? More than minimal? High risk? • What are the benefits?	 ____Yes ____No

14. Does the consent form contain the following elements?	
14.1 Purpose of the research	___Yes ___No
14.2 Expected duration of participation	___Yes ___No
14.3 Description of procedure to be followed	___Yes ___No
14.4 Random assignment to the trial treatments	___Yes ___No
14.5 Benefits to the participants	___Yes ___No
14.6 Alternative procedures/sources of treatment	___Yes ___No
14.7 Extent of confidentiality of records	___Yes ___No
14.8 Explanation of compensation and/or medical treatments in case of injury	___Yes ___No
14.9 Whom to contact for pertinent questions and/or for assistance in a research-related injury	___Yes ___No
14.10 Explanation that refusal to participate or discontinuance of participation at any time will involve no penalty or loss of benefits to which the subject is entitled	___Yes ___No
15. Do you have other concerns? Please explain.	___Yes ___No

_____
_____
_____

RECOMMENDATION:
_____Approval _____Modification required
_____Disapproval

Reason(s) for disapproval: _____

_____
Signature over printed name

2.D. NECHR's Decision Form

Meeting No.: ……../…….. Date (D/M/Y):……
Protocol number…… Assigned No.:……..

Protocol Title :

Principal Investigators:	
Institute:	
Elements Reviewed (FF 01-008) :	☐ Attached ☐ Not attached
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:
Decision of the meeting:	☐ Approved ☐ Approved with Recommendation ☐ Resubmission ☐ Disapproved

No.	Voting NECHR members	Decision			
		AP	AR	RES	DA

***Note**: AP - Approved; AR – Approved with recommendation;*
RES – Resubmission for re-review; DA – Disapproved

Signature:

……
Chairperson
Date:…….

2. E. Review of Resubmitted Protocol

Protocol No.:	Application No.: ☐☐☐ / ☐☐ - ☐☐

Protocol Title:		
Total Participants :		☐ 2nd Review ☐ 3rd Review ☐ 4th Review
Principal Investigator:		Tel.:
Initial Review Date:		Last Review Date:
NECHR Decision recorded in the meeting minute :		☐ Approved with minor changes or recommendation ☐ Major changes or recommendation need to be reconsidered
Opinion of the reviewer: ✧ Revision or Modification according to the recommendation ✧ What need to be further revised :		☐ Yes ☐ No: Explain:……... ……... ……
SIGNATURES: _____ Date:…… _____ Protocol Reviewer		
APPROVAL: _____ Date: …….. _____ Chairperson, NECHR **COMPLETION:** _____ Date:…… _____ Secretary, NECHR		

2. F. Information Sheet and consent form

INFORMATION SHEET

The information provided to the participants before getting the consent should be short, but clear enough for the participants to be able to rationalize their decision whether to participate in the study or not. It should be written in local language using simple words.

The information should include, but not limited to the followings:

1. Name of institution (s) and investigators conducting the study
2. Rationales of the study
3. Purposes of the study
4. Method of the study
5. The importance of the participants' participation
6. Anticipated risks or discomfort to the participants, both physical and psychological risks
7. Measures to take care of foreseeable risks
8. Direct benefits to the participants that might reasonably be expected. If there are no direct benefits expected, the participants should be made aware of.
9. If payment for the participation is applied, the process of payment through the duration of study should be clearly described.
10. Duration of their participation
11. Compensation or services provided for any risks or complications related to the study.
12. Any standard or alternative procedures or courses of treatment available, locally or elsewhere, that might be as advantageous to the participants as the procedures or treatment being tested
13. Indication that the participation is voluntary, and even if they have accepted to participate, the participants still have the rights to withdraw from the study at any time without any punishment of changes to the services they would otherwise receive.

14. Name(s) and contact address of attended physician(s) or contact person(s) in case of needs or emergency.

The Consent Form

The consent form can be separated from or combined with the information sheet. It should be made two copies, one for the participant and another one kept by the investigator. If written consent is considered unnecessary, the investigator should provide good reasons.

Below is an example of a consent form: Note that this is just an example of the consent form. The proponent is free to select any format as long as it contains essential statements and conveys the same meanings.

INFORMED CONSENT

You are invited to participate in the following study

Title of protocol:

Name of Institution

Investigators:

Sponsor:

Please sign the form below to indicate your consent.

I, undersigned ....., have read the information provided. All my questions related to the study and the participation in the study have been satisfactorily answered and explained. I understand the risks and benefits that may result to me from my participation. I understand that the participation to the study is completely voluntary and I can withdraw myself from the study at any time without penalty or loss of benefits I would otherwise be entitled.

On my own will, I volunteer to participate in the study entitled ..... of (name of institution) .....

Signatures:

Person giving consent ..... Date .....

1st Witness ..... Date .....

2nd witness ..... Date .....

Person obtaining consent ..... Date

3. A. **NECHR AGENDA FORM**

Date of Meeting:

Time:
Venue:

Items for Discussion
A. New Protocols for Discussion

Protocol Number	Title of Protocol……	Investigator	Sponsor	Reviewers

B. Protocol Amendment

Protocol Number	Title of Protocol……	Investigator	Sponsor	Reviewers

C. Expedited Review Reports

Protocol Number	Title of Protocol……	Investigator	Sponsor	Reviewers

D. Adverse Events Report

Protocol Number	Title of Protocol……	Investigator	Sponsor	Reviewers

E Continuing Study Reports

Protocol Number	Title of Protocol……	Investigator	Sponsor	Reviewers

F. End of Study Reports

Protocol Number	Title of Protocol……	Investigator	Sponsor	Reviewers

G. Other Matters

1.
2.
3.

4. A. Continuing Review Application Form

PROTOCOL No.:	ASSIGNED No.: ☐☐☐ / ☐☐-☐☐
PROTOCOL TITLE:	
INVESTIGATOR:	

ACTION REQUESTED:
- ❑ Renew - New participant accrual to continue
- ❑ Renew - Enrolled participant follow up only
- ❑ Terminate - Protocol discontinued

HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW?
- ❑ NO
- ❑ YES (Describe briefly in attached narrative)

SUMMARY OF PROTOCOL PARTICIPANTS:
- _____ Accrual ceiling set NECHR
- _____ New participants accrued since last review
- _____ Total participants accrued since protocol began

ACCRUAL EXCLUSIONS
- ❑ NONE
- ❑ MALE
- ❑ FEMALE
- ❑ OTHER (specify: _____)

IMPAIRED PARTICIPANTS
- ❑ None
- ❑ Physically
- ❑ Cognitively
- ❑ Both

HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?
- ❑ NO
- ❑ YES (Explain changes in attached narrative)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
- ❑ NO
- ❑ YES (Explain changes in attached narrative)

HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE NECHR'S EVALUATION OF THE RISK/BENEFIT ANALYSIS OF HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?
- ❑ NO
- ❑ YES (Discuss in the attached narrative)

HAVE ANY UNEXPECTED COMPLICATIONS OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW?
- ❑ NO
- ❑ YES (Discuss in the attached narrative)

HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST NECHR APPROVAL?
- ❑ NO
- ❑ YES (Discuss in the attached narrative)

INVESTIGATIONAL NEW DRUG/DEVICE
☐ NONE ☐ IND ☐ IDE
FDA No. ……..
Name: ……..
Sponsor: ……..
Holder: ……

IONIZING RADIATION USE (X-rays, radioisotopes, etc)
- ❑ None
- ❑ Medically indicated only

HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?
- ❑ NO
- ❑ YES (Identify all changes in the attached narrative)

HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW?
- ❑ NO
- ❑ YES (Identify all changes and provide an explanation of changes in the attached narrative)

CHANGE IN INVESTIGATOR?
- ❑ NONE
- ❑ DELETE:……..
- ❑ ADD: ……_____

HAVE ANY INVESTIGATORS DEVELOPED AN EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST?
- ❑ NO
- ❑ YES (Append a statement of disclosure)

SIGNATURES:

_____Date: ……_____

Protocol Chairperson (if applicable)

_____ Date: ……_____

.... INSTITUTE.... Medical Advisor

_____ Date: ……_____

..... INSTITUTE.... Director

_____NECHR Comment/Decision:

APPROVALS

_____Date:……_____

Chairperson, NECRH

COMPLETION

_____ Date:……_____

Secretary NECHR

4. B. Final Study Report Form

Protocol No.:	Assigned No.: ☐☐☐ / ☐☐-☐☐
Protocol Title :	
Principal Investigator:	
Phone number:	**E-mail address :**

Sponsor's Name		
Address:		
Phone :	**E-mail :**	
Study site(s):		
Total Number of study participants :		**No. of Study Arms:**
Number of participants who received the test articles:		
Study materials:		
Treatment form:		
Study dose(s):		
Duration of the study		
Objectives:		
Results: (Use extra blank paper, if more space is required.)		
Signature of P.I.:		Date:

4. C. Deviation / Non-Compliance / Violation Record

Application Number: ☐☐☐ / ☐☐ - ☐☐	Date:……
Study Title:	
Investigator	Contact No.:
Institution:	Contact No.:
Sponsor:	Contact No.:

☐ Deviation from protocol ○ Major ○ Minor	☐ Non-Compliance ☐ Violation
Description:	
NECHR's Decision:	
Actions taken:	Outcome:

Found by:…… Date:……..	Reported by:……. Date:…….

4.D. Participant Request Record Form

Date Received:	
Received by :	
Request from :	❑ Telephone call No……... ❑ Fax No……..…. ❑ Mailed letter / Date…… ……. ❑ E-mail / Date…… ❑ Walk-in / Date / Time…….. ❑ Other, specify …….
Participant's Name:	
Contact Address: Phone:	
Title of the Participating Study	
Starting date of participation :	
What are requested?	
Action taken: Outcome:	

4. E. Study Termination Memorandum

PROTOCOL NUMBER:		ASSIGNED No.: ☐☐☐ / ☐☐-☐☐	
PROTOCOL TITLE:			
PRINCIPAL INVESTIGATOR:			
PHONE :		E-MAIL:	
INSTITUTE:			
SPONSOR:			
NECHR APPROVAL DATE:		DATE OF LAST REPORT:	
STARTING DATE:		TERMINATION DATE:	
NO. OF PARTICIPANTS:		NO. ENROLLED:	
SUMMARY OF RESULTS			
ACCRUAL DATA:			

P.I.SIGNATURE:		DATE:

4.F. Serious Adverse Event Report

Principal Investigator:……..... Application No: ☐☐☐ / ☐☐ - ☐☐

Study Title:…….…… Protocol No.:

Name of the study medicine/device…….……..…… Report Date :…… ☐ initial ☐ follow-up Onset date:……

Sponsor:..…… Date of first use: ……..

Subject's initial/number:	Age:	☐ Male ☐ Female

Subject's history:	Laboratory findings:

SAE:	Treatment:
	Outcome: ☐ resolved ☐ on-going

Seriousness:	Relation to ○ Drug ○ Device ○ study
☐ Death	☐ Not related
☐ **Life Threatening**	☐ Possibly
☐ Hospitalization –○ initial ○ prolong	☐ Probably
☐ Disability / Incapacity	☐ Definitely related
☐ Congenital Anomaly	☐ Unknown
☐ Other……	

Changes to the protocol recommended?	☐ No ☐ Yes , attach proposal
Changes to the informed consent form recommended?	☐ No ☐ Yes , attach proposal

Reviewed by:…….....…… Comment:……..... .....……	Date:…… Action:……..... .....……

4. G . Checklist of a Monitoring Visit

Application No.: ☐☐☐ / ☐☐ - ☐☐	Date of the Visit:	
Study Title:		
Principal Investigators:		Phone:
Institute:	Address:	
Sponsor:	Address:	
Total number of expected subjects:	Total subjects enrolled:	
Are site facilities appropriate? ☐ Yes ☐ No	Comment:	
Are Informed Consents recent? ☐ Yes ☐ No	Comment:	
Any adverse events found? ☐ Yes ☐ No	Comment:	
Any protocol non-compliance /violation? ☐ Yes ☐ No	Comment:	
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:	
Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:	
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:	
Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:	
Duration of visit: …….hours	Starting from:	Finish:
Name of NECHR member/		

representatives and companion:	
Completed by:	Date:

5.A. Document Request Form

Name of Document requested:	Code:
Requested by:	Date:
☐ Chairperson ☐ Secretariat ☐ NECHR Member	
☐ Secretariat staff ☐ Authority ☐ Others……..	
Purpose of the request:	
Retrieved by:	Date:
Returned by:	Date:
Archived by:	Date:
Approved by:	Date:

5. B. Log of Requests for Copies of NECHR Documents

#	Documents requested	# of Copies	Name of Recipient	Signature of Recipient	Secretariat Initials	Date

5. C. Database Requirements

Files Required

1. SOPs and Guidelines
2. National and International Regulation
3. EC Membership Folder
    a. Individual file for each member and staff
        i. Appointment papers
        ii. Terms of reference
        iii. CV of NECHR member

iv. Training record
v. Confidentiality and conflict of interest agreement

4. Individual Protocol Folder
    a. Original Protocol Submitted
    b. Approved Revised Protocol
    c. CV of investigators
    d. Protocol related documents
    e. SAE reports
    f. Continuing review
    g. Communication related to protocol

5. SAE Files
6. Minutes and agenda of meetings
7. Communication records

7.A.Document History

(the first draft 0.1 of the SOP History should be produced as the output of the first circulation of the document and the final version is the version after the approval by the Chairperson which is 01.0)

Author –	Version	Date	Describe the main change
name	0.1	*dd-Mmm-yy*	first draft
name	0.2	*dd-Mmm-yy*	Second draft
name	01.0	*dd-Mmm-yy*	final version
name	01.1	*dd-Mmm-yy*	Minor changes
name	02.0	*dd-Mmm-yy*	Major changes
name	02.0	*dd-Mmm-yy*	No change (routine review)

7.B. Log of SOP Recipients

No.	Name of Recipients	SOP#	No. of Copies	Signature	Date
1	*Chairperson*	*SOP/001/01.0* *SOP/002/01.0*			

		SOP/003/01.0			
2	*Dr. XXXX*	*SOP/001/01.0* *SOP/002/01.0* *SOP/003/01.0*			

Glossary of terms and definition

1 Description of individual roles

Chairperson

A member of the NECHR who presides over a board meeting and is responsible for expedited approvals on behalf of the Board.

Coordinator (Site)

The person at the study site who is responsible for managing the study Sometimes, the Principal Investigator is also the site coordinator and manager.

NECHR

The NECHR is a body established to review and monitor health research involving human subjects. The primary purpose of such a review is the protection of the rights and welfare of the human subjects. In accordance with applicable national/international regulations, the NECHR has the authority to approve, require modifications to, or disapprove research.

The NECHR consists of at least one board with at least five regular members in addition to alternate members. Alternates are categorized and given equal status as regular members within the board (i.e., non-scientific or M.D, etc.). The composition of the membership must reflect a diversity of backgrounds sufficient to assure:

- expertise and experience to provide adequate review of research activities
- consideration of race, gender, and cultural backgrounds
- sensitivity to attitudes and concerns of the community and the patient population
- knowledge of applicable regulation, laws and standards of professional conduct and practice
- no member participates in the review process of any study project in which he/she has a conflicting interest
- no gender discrimination

NECHR Members

Nonemployee individuals serving as regular and alternate members on ..*INSTITUTE*..'s operational board (i.e., the IEC membership). This board is constituted in accordance with the NECHR membership requirements. Individuals qualified to vote at a duly convened ..*INSTITUTE*.. NECHR meeting

Investigational New Drug (IND)

Investigational new drug means a new substance, antibiotic drug, or biological product that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part.

Principal Investigator

Individual responsible for implementing and coordinating an investigational study

Secretariat

The NECHR staff who are responsible for the day-to-day administrative functions and duties which support the activities and responsibilities of the IEC members.

SOP Team

A selected group of ..*INSTITUTE*.. members and administrative staff who oversee the preparation, review and periodic revision of the ..*INSTITUTE*.. SOPs

Vice Chairperson

A member of the ..*INSTITUTE*.. NECHR who assists the Chairperson as needed in conducting meetings and expedited review

Vulnerable subjects

A category of research participants that includes children, prisoners, pregnant women, handicapped or mentally disabled persons and economically or educationally disadvantaged persons who are likely inclined to coercion or undue influence

2. Definition of Terms

Active study files

Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by the. NECHR.

Administrative documents

Documents include official minutes of Board meetings as described in SOP,NECHR meeting minutes and voting records and the standard operating procedures, both historical files and Master Files as described in the SOP, SOP distribution, implementation and file maintenance.

Deviation

Any instance in which the current approved NECHR. SOP cannot be or has not been followed.

Expedited approval

An IEC approval granted only by the Chairperson of the NECHR or a designated *NECRH* member (not the full Board) for “minor” changes to current NECHR approved research activities and for research which involves no more than minimal risk

Final report

An obligatory review of study activities presented as a written report to the *NECHR* after the last subject has completed all visits and all adverse experiences have been brought to appropriate resolution.

Complete, comprehensive written description of a completed trial that describes the experimental materials and statistical design, presentation and evaluation of the trial results and statistical analyses.

Historical file

A document file which was effectively used in the past and presently became obsolete or expired, but still had to be kept in a file for reference purposes.

Inactive study files

Supporting and approved documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communication and correspondence with the investigator, and reports (including but not limited to progress reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by NECHR for which a final report has been reviewed and accepted Inactive study files are archived for a minimum of three years following the completion of the study. These files can be retrieved as needed.

Investigational medical device

A medical device which is the object of clinical research to determine its safety or effectiveness

Master files

Original copies of documents such as SOPs, guidelines, instruction, manual with real signatures of preparers, reviewers and authorized persons are systematically stored in secured cabinets with limited access.

Medical Device

A medical device is any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-ocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kids for *in vitro* diagnosis of disease and other conditions, (for example, pregnancy).

Minutes

The official record of events, activities, and actions taken on agenda items presented to a duly constituted (quorum present) independent board review meeting. The minutes identify fully each protocol and/ or activity and record the outcomes of each voting action. The board votes separately on each collective set or each item submitted for review: protocol, consent form, investigator, and advertisement(s). The record notes the number for, number against, the number of abstaining votes, and the reason for the abstention(s), without identifying the individual member's names.

New Study

A study protocol including the informed consent, investigator's qualifications, information on the drug or device and advertisements (if applicable) presented to NECHR for approval for the first time and not previously approved by this Board. This includes re-application for those studies denied approval by NECHR.

Non-compliance record

A list containing the identity of investigators who are considered by the Board to be non-compliant with national/international regulations or who fail to respond to the Board's requests, and the incident(s) justifying the reason for the determination of non-compliance.

Non-significant Risk Device (NSR)

A non-significant risk device is an investigational device that does not pose a significant risk.

Progress Report

An ongoing review of each investigator's study activities presented as a written report to obtain extended approval for the study from the NECHR. Generally, these reports are due annually with the NECHR sending a written notification reminding the investigator of this obligation. More frequent reports may be requested at the discretion of the NECHR.

Protocol Amendment

A change to the study protocol during the planning or course of the trial

The amendment is a foreseen change to the study plan that requires formal approval by the sponsor.

Quorum

Attendance required to arrive at a decision at any convened meeting of the board. If 5 is the minimum number of members prescribed in the SOP, 3 of the regular (or alternate) members, including at least one physician and one layperson constitutes a quorum and should be maintained throughout the discussions and voting portions of the meeting.

Significant Risk Device (SR)

A significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the subject, (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the subject, (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the subject, or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of the participants.

3 Addition / Correction of terms

- Members are encouraged to propose any additional terms or make correction of any terms defined in this SOP at any time, if he/she feels clarification should be made.
- Write your proposal.
- Submit your proposal to the IEC/IRB secretariat.

5.4 Approval of the addendum

- IEC/IRB secretariat shall bring the proposal to a meeting.
- The proposal shall be discussed for further opinion.
- Agreement and approval shall be made at the meeting.

6. Glossary

none

7. ANNEX

none

8. Reference

8.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

8.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.