Supersedes:	Previous NCH-IRB SOPs
Prepared by:	2017 NCH-IRB SOP Committee
Reviewed by:	**NATIONAL CHILDREN'S HOSPITAL INSTITUTIONAL REVIEW BOARD (NCH-IRB)**
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Approval Date	

2. REVIEW PROCEDURES

2.1 Management of Protocol Submissions
2.2 Use of Study Assessment Forms
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2.1. MANAGEMENT OF INITIAL PROTOCOL SUBMISSION

2.1.1. Purpose

To describe the **National Children's Hospital-Institutional Review Board (NCH-IRB)** procedure for managing the submission of the initial protocol package for review – from the time of receipt to filing of the initial protocol package in the Active File storage cabinet.

2.1.2. Scope

This procedure applies to all protocols submitted to the NCH-IRB for ethical review.

The NCH-IRB accepts the following protocols for review:

1) NCH funded researches,
2) Researches to be done at NCH,
3) Researches referred from the PNHRS, PCHRD, DOST, PHIC, PHREB, DOH, FDA, CHED, industry organizations, etc. on the condition that the host hospital/institution where the proposal will be done accepts the review of NCH-IRB and agrees to abide by the rules and regulations that the NCH-IRB follows. The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the NCH-IRB may deem necessary. These conditions should be written in a document and signed by other hospitals/ institutions that accept NCH-IRB review.

2.1.3. Responsibility

The NCH-IRB Secretariat manages all protocol submissions to the NCH-IRB. It covers the actions to be done from the time of submission to the filing of the initial protocol package in the Active Study File cabinet.

2.1.4. Process Flow/Steps

NO	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Receive the initial protocol package for review and check the completeness of the documents	Staff	20 days before the meeting
2	Assign a permanent code to the protocol package		
3	Determine the type of review and the primary reviewers	Chair/ Member Secretary	3 days

4	Prepare the protocol review package for distribution to the primary	Staff	
5	Log the received protocol package in the Protocol Database		
6	File the initial protocol package in a properly labeled Protocol File folder and place it in the Active Study File		

2.1.5. Detailed Instructions

2.1.5.1. Receive the initial protocol package for review and check the completeness of the documents submitted

- Ensure that the Review Application Form and the Protocol Summary Sheet are completely filled up, signed and dated by the researcher.
- For research protocol of resident physicians (on training), and fellows, an endorsement from the department and the technical review committee is required.
- For doctoral or master's thesis of NCH employees or other researchers (not connected with the hospital), check for approval and endorsement from the thesis adviser/panel and institution's section head, respectively.
- All NCH-funded protocols need technical review. The Technical Review Committee should have addressed the technical issues in the study protocol.
- For non-NCH funded protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.
- Upon submission of the initial protocol for NCH-IRB review, the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains a Protocol Summary Sheet

2.1.5.2. Assign a permanent code to the protocol package

For efficient file management, it is necessary to use a unique identifier to refer to this file, the Protocol Code Number. This code number is given as follows: NCH IRB-yyyy-nn-type of study (*nn- chronological number based on order of receipt*).

For example, if the protocol entitled "Clinical Drug Trial of XYZ on Pediatric Patients" is the first protocol received in 2017, the code ***NCH-IRB 2017-01-CT*** *should be used to identify this protocol.* The

code will be communicated to the researcher/principal investigator in all communications regarding the protocol.

2.1.5.3. Give a duplicate copy of the review application form to the person submitting the package.
Instruct the person submitting the package to inform the researcher/PI to use the Protocol Code Number to identify the protocol in all submissions and in all his/her communications to the NCH-IRB.

2.1.5.4. Determine the type of review and assign primary reviewers
There are three (3) types of review:

a) EXEMPT FROM REVIEW – for negligible risk protocols
- Research about public behavior (*voting trends, opinion surveys, etc.)*
- Evaluation of public programs by the agency itself
- Quality control studies by the agency itself
- Standard educational tests and curriculum development
- Surveillance functions of DOH
- Historical and cultural events
- Research involving large statistical data without identifiers
- Research not involving humans or human data

b) EXPEDITED REVIEW – for minimal/low-risk protocol, health research that requires personal information:
- About a topic that should not result in causing social stigma
- Does not involve vulnerable populations
- Retrospective studies using anonymized data from medical records
- Laboratory research that uses anonymized human tissue/specimen

c) FULL-BOARD REVIEW – for medium to high-risk protocols and protocols from SJREB.
- Human health research involving medium to high risks to human participants
- Intervention studies involving experimental treatments like clinical trials
- Involve vulnerable populations who should be protected
- Involve private information that may cause stigma

The Chair/Member-Secretary designates at least two NCH-IRB members to be the primary reviewers of the protocol regardless of whether the type of review is expedited or full board.

Primary reviewers are selected on the basis of expertise related to the protocol.
The medical/scientific reviewer analyzes the scientific and ethical aspects of the protocol using the Protocol Assessment Form while the non-medical member focuses on the ICF and informed consent procedure using the Informed Consent Assessment Form.

If the NCH-IRB membership does not have the needed expertise, the Chair/Member Secretary chooses from the roster of Independent Consultants. If none is available, a consultant with the needed expertise is recruited as per SOP on Selection of Independent Consultant *(SOP No. 1.2).*

2.1.5.5. Prepare the protocol review package for distribution to the primary reviewers

- The timeline from receipt of complete package to distribution to primary reviewers is 3 calendar days.
- The initial protocol review package consists of all the documents in the initial protocol package plus blank copies of the Protocol Assessment Form**,** with the transmittal letter to the primary reviewers.

2.1.5.6. Log the received protocol package in the Protocol Database

- After ensuring the completeness of the initial protocol package, log the pertinent data in the electronic protocol database.
- As soon as subsequent data is available, complete the required protocol details in the protocol database.

2.1.5.7. File the initial protocol package in a properly labeled Protocol File folder and place it in the Active Study File cabinet

- Write the NCH-IRB Protocol Code Number of the protocol on the side of the file binder. On the front cover of the protocol binder, write the following:
  - NCH-IRB Protocol Code Number
  - Name of the Principal Investigator and Co-Investigator/s
  - Name of the Sponsor
  - Date Received

- Attach a protocol file index that should serve as a Table of Contents of each protocol file.
- File the properly-labeled protocol file folders in the appropriate shelf of the storage cabinet for active study files taking note of the sequence of protocol code numbers on the file binders.

2.2. USE OF STUDY ASSESSMENT FORMS

2.2.1. Purpose

To describe the NCH-IRB procedures related to the use of study assessment forms in ethics review

2.2.2. Scope

This SOP applies to the use of the Study Assessment Forms in the review and assessment of protocols and related documents submitted to NCH-IRB for its initial review and approval.

The NCH-IRB uses two Study Assessment Forms that are accomplished by individual primary reviewers. All comments, evaluation, recommendations and the initial decision of each reviewer regarding a protocol are all noted in these two Forms.

The two Study Assessment Forms are designed to standardize the review process and to facilitate reporting of recommendation and comments given to each individual protocol and related documents. These are:

a. Protocol Assessment Form
b. Informed Consent Assessment Form

2.2.3. Responsibility

It is the responsibility of the NCH-IRB reviewers to fill-in the assessment forms after reviewing each study protocol and submit to the Secretariat within 7 days (for expedited protocols) or within 14 days (for full board protocols).

The Secretariat is responsible for reminding the primary reviewers to submit the accomplished assessment forms and update the protocol folders.

2.2.4. Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE
1	Fill up the Study Assessment Forms when reviewing the study protocol and related documents.	Primary Reviewers
2	Submit accomplished Study Assessment Forms to the Secretariat within 7 days for expedited protocols or within 14 days for full board protocols after receipt of documents	Primary Reviewers
3	Compile accomplished assessment forms for review by the Chair/Member-Secretary	Staff

4	File copies of accomplished assessment forms and other review documents in the protocol binder	Staff

2.2.5. Detailed Instructions

2.2.5.1. Fill up the Study Assessment Forms when reviewing the study protocol and related documents.

- The Primary Reviewers read the protocol and related documents, and complete the assessment forms.
- Primary Reviewers should also do literature review to ensure updated knowledge about the protocol.
- The NCH-IRB primary medical or primary scientific reviewer accomplishes the Protocol Assessment and the Informed Consent Assessment Form while the primary non-medical or non-scientific reviewer focuses on the Informed Consent Assessment Form only.
- The Protocol Assessment Form allows review of the technical and ethical issues as follows:
  - Rationale and significance of the study
  - Objectives of the study
  - Review of literature
  - Sample size
  - Methodology and data management
  - Inclusion/exclusion criteria
  - Control arms (*placebo, if any*)
  - Withdrawal or discontinuation criteria
  - Vulnerability determination
  - Risk/ benefit assessment

- The Informed Consent Assessment Form enables review of the following:
  - Full disclosure of information, including risks
  - Benefits that may be derived from the study
  - Use of understandable language, with appropriate translation
  - Voluntary participation
  - Confidentiality
  - Appropriate person to sign the consent form

- If an Assent Form is required, it should be reviewed, together with the informed consent, to ensure that the proper form is available, the appropriate signature is required.
- Review the qualifications of the PI and the research team to include the following:

- Education and specialty
- GCP training for all types of studies except for chart review
- GRP training for cross-sectional studies using chart review
- GCP training for at least two days is required for sponsored clinical trials

- Review the sites where the study will be conducted.

2.2.5.2. Submit accomplished Study Assessment Forms to the Secretariat within 7 days for expedited protocol or within 14 days for full board protocols after receipt of documents

The Primary Reviewers accomplish, sign and date the assessment forms and submit to the Secretariat within 7 days for expedited protocol or within 14 days for full board protocols from date of receipt of the protocol review package.

2.2.5.3. Compile accomplished assessment forms for review by the Chair/Member Secretary

- The Secretariat checks whether the forms are complete, compiles the completed assessment forms and submits these to the Member-Secretary/Chair.
- The Member-Secretary/Chair reviews the compiled checklists. If the protocol is for expedited review, the Member-Secretary/Chair determines if there are no conflicting recommendations and if there is an agreement in the review/decision. If there are conflicting recommendations and/or disagreements in the review decision, the Member-Secretary/Chair forwards the protocol for Full-Board review.

2.2.5.4. File copies of accomplished assessment forms and other review documents in the protocol binder

File accomplished assessment forms in the protocol binder and update the Protocol File Index by adding the Protocol Assessment Form and the Informed Consent Assessment Form with the date of submission.

2.3. EXEMPT FROM REVIEW

2.3.1. Purpose

To describe the NCH-IRB procedures for the review of protocols that qualify for exemption from review.

2.3.2. Scope

This SOP applies to the review of a study protocol submitted to the NCH-IRB that qualifies for exemption from review.

2.3.3. Responsibility

The Chair is responsible for the assessment whether the submitted protocol qualifies for exemption from review.

2.3.4. Process Flow/ Steps (to be done within 7 days)

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Review a study protocol applying for exemption from review	Chair	To be done within 7 days
2	Issue Certificate of Exemption or recommend expedited or full-board review		
3	Prepare a report of protocols that are exempt from review to full-board	Secretariat	
4	Communicate the NCH-IRB decision to the PI	Staff	
5	File copy of the documents in the protocol binder and update protocol database for exemption from review		

2.3.5. Detailed instructions

2.3.5.1. Review a study protocol applying for exemption from review

- The Chair who does not have any conflict of interest should review the study protocol applying for review exemption. If the Chair has conflict of interest, the Member-Secretary should review the study protocol applying for review exemption.

- The Chair should then evaluate the study protocol using the Exemption Criteria.

2.3.5.2. Issue Certificate of Exemption or recommend expedited or full-board review

- If the protocol qualifies for exemption from review, the Chair submits the results of the assessment to Secretariat for the NCH-IRB staff.
- The NCH-IRB staff prepares a Certificate of Exemption from Review.
- If the protocol does not meet the Exemption Criteria, the Chair reclassifies the protocol for expedited or full-board review then follows the process flow for expedited or full-board review.

2.3.5.3. Prepare a report of protocols that are exempt from review to full-board

The NCH-IRB Staff prepares a report to the next full board meeting to include details of all protocols exempted from review.

2.3.5.4. Communicate the NCH-IRB decision to the PI

- The NCH-IRB Staff prepares Certificate of Exemption from Review and forwards to the Chair for signature.
- The NCH-IRB Staff issues the Certificate of Exemption to the Principal investigator.

2.3.5.5. File copy of the documents in the protocol binder and update protocol database for exemption from review

- Prepare a binder to contain all protocols exempt from review.
- File the properly-labeled binder in the appropriate shelf of the storage cabinet.
- Update protocol database for exemption from review.

2.4. EXPEDITED REVIEW

2.4.1. Purpose

To describe the NCH-IRB procedures for the review of protocols that qualify for expedited review.

2.4.2. Scope

This SOP applies to the initial and continuing review and approval of study protocols with minimal risks to study participants. In general, Expedited Review is done

- in minimal/low risk health research that requires personal information (*ex. review of medical records*)
- about a topic that should not result in causing social stigma
- in retrospective studies using anonymized data
- in health studies using simple questionnaires without identifiers
- in laboratory research that uses anonymized human tissue/specimen

2.4.3. Responsibility

Expedited review is the responsibility of assigned primary reviewers to assess a protocol. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol.

2.4.4. Process Flow/ Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Determine that the submission qualifies for expedited review.	Chair/ Member-Secretary	1 day
2	Assign primary reviewers (*medical/scientific and a non-medical/non-scientific members*).		
3	Send the protocol package to the primary reviewers	Staff	7 days
4	Review the documents with the use of the assessment forms.	Primary Reviewers	

5	Return the accomplished assessment forms to the Secretariat.		
6	Collate and review the assessment forms to take appropriate action.	Chair/Member Secretary	7 days
7	Communicate the NCH-IRB decision (if decision is minor revision) to the PI	Staff	1 day
8	Prepare a list of all expedited review results and report to full board	Secretariat	1 day
9	File copies of the documents in the protocol file folder and update the protocol database	Staff	

2.4.5. Detailed instructions

2.4.5.1. Determine that the submission qualifies for expedited review.

- FOR INITIAL REVIEW: The Chair checks if the submitted protocol qualifies for expedited review. The following are types of protocols that can be subjected to expedited review after initial submission:
  - Protocols of a non-confidential nature (*not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma*), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities or cause psychological stress to the people involved.
  - Protocols **not** involving vulnerable subjects (*individuals whose willingness to volunteer in a study may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent*).
  - Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (*e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner*).
  - Research involving data, documents or specimens that have been previously collected
  - Proposed continuing review of previously expedited protocols, minor protocol amendments and end of study reports.

- FOR RESUBMITTED DOCUMENTS: NCH-IRB decision for minor modification qualifies for expedited review by the Chair.

- SUBMISSIONS AFTER INITIAL APPROVAL may qualify for expedited review as follows:
  - Administrative revisions, such as correction of typing errors
  - Addition or deletion of non-procedural items, such as the addition/change in study personnel or changes in their address or contact number, change in laboratories, and the like.
  - The research activity includes only minor changes from previously approved protocol.
  - Minor protocol amendments that do not change the risk/benefit assessment
  - Progress/Final reports that were initially reviewed by expedited review and that do not deviate from approval given by the NCH-IRB.

2.4.5.2. Assign primary reviewers *(medical/scientific and a non-medical/non-scientific members)* to review the submitted documents.

- Assign a Medical/Scientific Reviewer *(NCH-IRB member or Independent Consultant)* to review the scientific and ethical merits of the protocol related documents.
- Assign a non-medical/non-scientific member to review the ICF.

2.4.5.3. Send the protocol package to the primary reviewers

- The NCH-IRB Staff contacts the designated Primary Reviewers to determine if they can review the protocol documents within the 7 day deadline. If not, other primary reviewers are identified by the Chair.
- The Staff prepares the notice to the Primary Reviewers, the protocol package and the corresponding assessment forms and forwards them to the designated reviewers.

2.4.5.4. Review the documents with the use of the assessment forms.

- The Primary Reviewers read the protocol and related documents, and complete the assessment forms. The NCH-IRB primary medical reviewer accomplishes both the protocol and ICF assessment forms while the primary non-medical reviewer evaluates informed consent documents by using the Informed Consent Assessment Form.
- The Primary Reviewers decide whether the protocol can be approved, modified or disapproved.
- When minor modification is required, the protocol documents are returned for the researchers to revise the documents and resubmit to the NCH-IRB for approval.

- Disapproved protocols and protocols with major modification are automatically forwarded to full board for discussion and decision. Disapproval cannot be done at the expedited level.

2.4.5.5. Return the accomplished assessment forms to the Secretariat

- The Primary Reviewers sign and date the assessment form/s and return them to the Secretariat within 7 days from receipt of the protocol review package.
- The Secretariat checks completeness of the assessment forms and forwards them to the Member-Secretary to recommend appropriate NCH-IRB follow up action.

2.4.5.6. Collate and review the assessment forms to take appropriate action.

- The Chair/Member-Secretary reviews the completed assessment forms to determine if there is agreement in the review/decision. The comments and decision are consolidated and communicated to the PI.
- If there are conflicting recommendations and/ or disagreement in the review decision or when the protocol is disapproved, the Member-Secretary includes the protocol in the next full board meeting for discussion and decision of full board.

2.4.5.7. Communicate the NCH-IRB decision to the PI.

- The NCH-IRB Staff communicates approval to the PI and uses the Certificate of Approval Form *(Form 2.6).*
- In case revision is required, the comments are sent to the PI to comply with the required modifications. The PI resubmits the documents to the NCH-IRB using the notification form *(Form 2.5*).

2.4.5.8. Prepare a report on results of expedited review and protocol for full board review.

- The NCH-IRB Staff prepares a list of protocols approved through expedited review and the Member-Secretary reports them during the full board meeting.
- The report is included in the Minutes of the meeting.

2.4.5.9. File a copy of the documents in the protocol file folder and update the protocol database.

- The NCH-IRB Staff files copies of the approved documents in the protocol file folder.
- Update the protocol file index of the protocol file folder.
- The NCH-IRB Staff updates the protocol database.

2.5. FULL BOARD REVIEW INCLUDING SUBMITTED PROTOCOLS FROM SJREB

2.5.1. Purpose

To describe the NCH-IRB procedures when the protocol submissions are classified for full board review

2.5.2. Scope

This SOP applies to the NCH-IRB full board review and approval of study protocols during initial and continuing review.

2.5.3. Responsibility

Full board review is the joint responsibility of all NCH-IRB members who review and make decisions on the protocol related documents during a convened full board meeting.

In general, full board review is done for protocols that involve medium to high risk interventions to human participants like experimental treatments in clinical trials that may involve vulnerable human subjects.

2.5.4. Process Flow/ Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Determine if the submission should undergo full board review.	Chair	3 days
2	Assign primary reviewers (*medical/scientific and a non-medical/non-scientific members*).		
3	Send the protocol package to the primary reviewers	Staff	
4	Review the documents with the use of the assessment forms.	Primary Reviewers	14 days

5	Return the accomplished assessment forms to the Secretariat.		
6	Discuss and decide on the protocol and related documents	Chair, Member-Secretary and Members	during a convened full board meeting
7	Communicate the NCH-IRB decision to the PI	Staff	Within 2 days after the meeting
8	File copies of the documents in the protocol file folder and update the protocol database	Staff	1 day

2.5.5. Detailed Instructions

2.5.5.1. Determine if the submitted protocol documents should undergo full board review.

- The Chair screens the protocol to identify those that should be discussed at full board.
- FOR INITIAL REVIEW: The Chair goes over the submitted protocol and decides if it should undergo full board review based on assessment of risks.
- The following are types of protocols that should be reviewed at a convened full board meeting:
  - Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)
  - Phase 4 intervention research involving drugs, biologics or device
  - Protocols including questionnaires and social interventions that are confidential in nature *(about private behavior, e.g. related to sexual preferences etc.; or about sensitive issues that may cause social stigma, psychological, legal, economic and other forms of social harm)*
  - Intervention protocols involving vulnerable subjects *(patients with incurable diseases, persons in nursing homes, patients in emergency situations, ethnic minority groups, homeless persons, refugees, minors and those incapable of giving consent)* that require additional protection from the NCH-IRB during review
  - Protocols that involve collection of identifiable biological specimens from vulnerable groups, etc.

- Multi-center studies involving NCH as a site. The protocols come from SJREB.
- Protocols involving vulnerable populations

- FOR RESUBMITTED DOCUMENTS: NCH-IRB decision with major modification of documents *(protocol, ICF, etc.)* requires full board review of revisions.
- The following CONTINUING REVIEW SUBMISSIONS should undergo full board review as follows:
  - Amendments that involve major changes from previously approved protocol or consent form *(major changes in the inclusion/exclusion criteria, safety issues, etc.)*
  - Major amendments that change the risk/benefit ratio
  - Major protocol violations
  - Progress reports of ongoing studies that involve medium to high risks to human subjects/participants
  - Onsite SAEs or SUSARs that involve safety issues.

2.5.5.2. Assign primary reviewers *(medical/scientific and a non-medical/non-scientific members)* to review the protocols.

The Chair:

- Assigns a Medical or Scientific Reviewer (*NCH-IRB member or Independent Consultant)* to review the scientific and ethical merits of the protocol related documents.
- Assigns a non-medical or non-scientific member to review the ICF.

2.5.5.3. Send the protocol package to the primary reviewers

- The NCH-IRB Staff contacts the designated Primary Reviewers to determine if they can review the protocol documents within the 14-day deadline. If not, other primary reviewers are identified by the Chair.
- The Staff prepares the notice to the Primary Reviewers, the protocol package and the corresponding assessment forms and forwards them to the designated reviewers.

2.5.5.4. Review the documents with the use of the assessment forms.

- The Primary Reviewers read the protocol and related documents, and complete the assessment forms. The NCH-IRB primary medical reviewer accomplishes both the protocol and ICF assessment forms while the primary non-medical reviewer evaluates informed consent documents by using the Informed Consent Assessment Form.

- The Primary Reviewers recommend the type of decision for initial review of protocol related documents:
  - Approved
  - Minor modification required
  - Major modification required
  - Disapproved

- Primary reviewers should also check the CV or information about the investigators *(including GCP training for clinical trials),* the study sites and other protocol related documents, including advertisements:
  - Consider whether study and training background of the principal investigator are related to the study.
  - Check for disclosure or declaration of potential conflict of interest.
- Determine if the facilities and infrastructure at study site are suitable for the study.

2.5.5.5. Return the accomplished assessment forms to the Secretariat

- The Primary Reviewers sign and date the assessment form/s and return them to the Secretariat within 14 days from receipt of the protocol review package.
- The Secretariat checks completeness of the assessment forms and forwards them to the Member-Secretary who includes it in the agenda of the next full board meeting.

2.5.5.6. Discuss and decide on the protocol and related documents during a convened full board meeting.

- Conduct a full board meeting to discuss and make a decision about the protocol and related documents. *(Refer to SOP on Conduct of Review Meeting)*
- The members of the NCH-IRB attending the full board meeting have to approve the following:
  - Principal and Co Investigators and members of the research team
  - Protocol
  - Informed Consent
  - Advertisements or recruitment materials
  - Study sites covered by the application

- The majority vote of NCH-IRB members on specific items is the basis for the decision as follows:
  - Approval (when no further modification is required)

- Minor modification *(requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.)*
- Major modification *(requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)*
- Disapproval *(due to ethical or legal concerns)* Reasons for vote of disapproval should be noted in the minutes and communicated to the PI.
  Members vote by writing their decision on a piece of paper and collected by the Member-Secretary who reads and tallies the vote.

- All deliberations and decisions regarding a protocol are noted in the meeting minutes. *(Refer to SOP on Preparation of Meeting Minutes)*

2.5.5.7. Communicate the NCH-IRB decision to the PI and allocate 15 days for the PI to comply.

- All NCH-IRB decisions are communicated to the PI within two days after the full board meeting.

  - **APPROVAL**:
    The NCH-IRB Staff prepares the Certificate of Approval to be signed by the Chair.

  - **MINOR MODIFICATION**:
    The NCH-IRB Staff prepares the Notification Letter to inform the PI of the required revisions in the protocol, ICF or any related document. The resubmitted documents undergo Expedited Review before approval is granted. The Chair reviews and checks compliance to recommendations of the resubmitted documents, before granting approval.

  - **MAJOR MODIFICATION**:
    The NCH-IRB Staff prepares the Notification Letter to inform the PI of a required revisions in the protocol, the ICF or related document. The resubmitted documents are referred to Primary Reviewers and discussed at Full Board Review.

  - **DISAPPROVAL**:
    The NCH-IRB Staff prepares the Notification Letter to inform the PI of NCH-IRB decision. The reasons should be clearly stated in the notice.

(Refer to SOP on Communicating NCH-IRB Decisions to the Researcher/PI)

2.5.5.8. File copies of the documents in the protocol file folder and update the protocol database.

- The NCH-IRB Staff files copies of the approved documents in the protocol file folder.
- The NCH-IRB Staff update the protocol file index of the protocol file folder.
- The NCH-IRB Staff updates the protocol database.

2.6. REVIEW OF RESUBMISSION

2.6.1. Purpose

To describe the procedures of NCH-IRB when the protocol resubmissions are received.

2.6.2. Scope

This SOP applies to the NCH-IRB review and approval of study protocols recommended for minor or major modifications during initial and continuing review.

2.6.3. Responsibility

It is the responsibility of the NCH-IRB Chair to classify resubmitted protocols for expedited or full board review.

It is the responsibility of the Chair to review the resubmitted documents to determine if they have complied with the required modifications before granting approval during expedited review or a responsibility of the primary reviewers to recommend approval of protocols with major modification to full board.

It is the responsibility of NCH-IRB members to approve resubmitted protocols with major modification after discussion.

2.6.4. Process Flow/ Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE

1	Receive the resubmitted protocol package from the PI.	Staff	1 day
2	Send the protocol package to the primary reviewers.		7 days
3	Review if the resubmission complied with the required modification	Primary Reviewers (*for Full Board Review*) Chair (*for Expedited Review*)	
4	Submit assessment forms to the Staff		
5	Discuss and decide on major modifications	Chair, Member-Secretary and Members	During the Full Board
6	Accomplish the Certificate of Approval and communicate the NCH-IRB decision to the PI	Staff	2 days
7	File copies of the documents in the protocol file folder and update the protocol database	Staff	

2.6.5. Detailed Instructions

2.6.5.1. Receive the resubmitted protocol package

The NCH-IRB staff receives the resubmitted protocol documents from the PI

2.6.5.2. Send the protocol package to the following:

Chair for Expedited Review:

- The NCH-IRB staff sends the package to the Chair.
- The NCH-IRB staff logs the protocol documents in the Log for Outgoing Documents.

Primary Reviewers for Full Board Review

- The NCH-IRB staff sends the package to the **Primary Reviewers**.
- The NCH-IRB staff logs the protocol documents in the Log for Outgoing Documents.

2.6.5.3. Review if the resubmission complied with the required modification

The Chair/Primary Reviewers review/s the resubmitted documents and compares it with the requirements for modification.

2.6.5.4. Return the documents with a decision after expedited review

- The Chair/Primary Reviewers return/s the resubmission package indicating decision.
- The Chair/Primary Reviewers approve/s the resubmitted documents if the PI has substantially complied with the required modifications.

2.6.5.5. Discuss and decide on major modifications

- Primary reviewers resend their assessment of major modifications during full board discussion.
- NCH-IRB members decide on the recommendation for approval.

2.6.5.6. Accomplish the action letter or Certificate of Approval and communicate the NCH-IRB decision to the PI

- The NCH-IRB decision is communicated to the PI.
  - FOR APPROVED RESUBMITTED PROTOCOLS, the NCH-IRB staff prepares the Certificate of Approval with signature of the Chair.
  - FOR PROTOCOLS WITH MINOR OR MAJOR MODIFICATION, the NCH-IRB Staff prepares the Action Letter with signature of the Chair.

2.6.5.7. File copies of the documents in the protocol file folder and update the protocol database.

- The NCH-IRB Staff updates the protocol database.
- The NCH-IRB Staff files copies of the approved documents in the protocol file folder.
- Update the protocol file index of the protocol file folder.