Initial Review Procedures Forms

Form 2.1 Application for Initial Review

Form 2.2 Protocol Summary Sheet

Form 2.3 Protocol Evaluation Form

Form 2.4 Informed Consent Evaluation Form

Form 2.5 Notice for Protocol Modification (for initial and continuing review)

Form 2.6 Certificate of Approval

Form 2.7 Certificate of Exemption from Ethics Review

Form 2.8 Protocol Resubmission Form

FORM 2.1

APPLICATION FOR INITIAL REVIEW

(To be filled by investigator)

NCH-IRB Protocol Number:		Submission Date:	

Protocol Title:	

Type of Research	☐	Clinical Research	☐ Clinical Trial	☐	Laboratory Research
	☐	Genetic Research	☐ Socio-behavioral	☐	Public health
	☐	Others: _____			

Study Duration	
Sponsor *(if applicable)*	
Principal Investigator:	

Telephone number:		Fax :	
E-mail:		Preferred means of contact	☐ Phone ☐ Fax ☐ Email
Institution			

Are you an employee of the sponsor? *(if applicable)*	☐	Yes	☐	No
Did you do consultancy or part time work for the sponsor? *(if applicable)*	☐	Yes	☐	No
In the past year, did you receive Php250,000 or more from the sponsor? *(if applicable)*	☐	Yes	☐	No
Other ties with the sponsor: *(if applicable)*				

Ethical Responsibility and COI Statement

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

PI Signature:	

Documents submitted:

- ☐ Protocol summary
- ☐ Patient information form
- ☐ Informed consent form
- ☐ Investigator brochure
- ☐ Case report forms (CRF)
- ☐ Research team list
- ☐ Advertisement
- ☐ CVs
- ☐ GCP certificate
- ☐ GRP certificate
- ☐ Study budget
- ☐ Payment of fees

Others:

- ☐ Revised protocol
- ☐ Revised consent form
- ☐ Amendments
- ☐ Technical Review Assessment Form/Certification
- ☐ Recommendation for submission (Dept.& Adviser for Pediatric Residents)

Received by NCH-IRB Secretariat:_____
(*Name and Signature*)

Date:

FORM 2.2

PROTOCOL SUMMARY SHEET

(To be filled by investigator)

NCH-IRB Protocol No:	Title

Principal Investigator	Sponsor (if applicable)

Rationale	
Objectives	
Study Design/ Methodology	
Inclusion Criteria	
Exclusion Criteria	
Data Analysis Plan	
Study Outcomes	

Ethical Considerations

FORM 2.3

PROTOCOL EVALUATION FORM

(To be filled up by primary reviewer)

Instructions: Please do literature search to update your knowledge about this protocol

NCH-IRB Protocol No.		Date:	
Protocol Title:			
Principal Investigators:			
Institution		Contact no./ Email	
Co – PI/ Members of the Research Team:		Contact no./ Email	
Total No. of Participants:		No. of Study Sites:	
Expected no. from your site/s			
Sponsor		Contact No/ Email	
Duration of the Study:		Status: ☐ New ☐ For renewal of approval	
Reviewers:			

☐ Intervention ☐ Epidemiology ☐ Observational study
☐ Document review ☐ Case study ☐ Genetic
☐ Social Survey ☐ Others, specify ☐ Others: (specify)

Review Type ☐ Full Board ☐ Expedited ☐ Exempt

Description of the Study in brief: Mark (✓) whatever applies to the study.

	Randomized		Drug		Use of genetic materials
	Double-blind		Medical Device		Multi-center study
	Single-blind		Vaccine		Global protocol
	Open-label		Diagnostics		Sponsor-initiated

	Observational		Questionnaire		Investigator-initiated

A. PROTOCOL DOCUMENT REVIEW

		Comments/what should be improved?
1.	Objectives of the Study ☐ Clear ☐ Not Clear	
2.	Need for Human Participants ☐ Clear ☐ Not Clear	
3.	Background Information ☐ Sufficient ☐ Not sufficient	
4.	Methodology ☐ Clear ☐ Not Clear	
5.	Sufficient number of participants? ☐ Yes ☐ No	
6.	Control Arms (placebo, if any) ☐ Yes ☐ No	
7.	Data Analysis plan ☐ Appropriate ☐ Not appropriate	
8.	☐ Defined ☐ Incomplete ☐ Not defined	
9.	Level of risk ☐ Negligible ☐ Low-medium ☐ High	
10.	Risks assessment ☐ Appropriate ☐ Not appropriate	
11.	Benefits Assessment ☐ Appropriate ☐ Not appropriate	
12.	Inclusion criteria ☐ Appropriate ☐ Not appropriate	
13.	Exclusion Criteria ☐ Appropriate ☐ Not appropriate	
14.	Withdrawal Criteria ☐ Appropriate ☐ Not appropriate	
15.	Involvement of Vulnerable Participants ☐ Yes ☐ No	
16.	Protection of Vulnerable Participants ☐ Appropriate ☐ Not appropriate	
17.	Voluntary, Non-Coercive recruitment of participants ☐ Yes ☐ No	
18.	Are the qualifications and experience of the participating investigators, research team	

appropriate? ☐ Yes ☐ No	
19. Disclosure of Potential Conflicts of Interest ☐ Yes ☐ No	
20. Facilities and infrastructure of participating sites ☐ Yes ☐ No	
21. Community Consultation ☐ Yes ☐ No ☐ NA	
22. Involvement of local researchers and communities in the protocol preparation and implementation ☐ Yes ☐ No ☐ NA	
23. Contribution to local capacity building ☐ Yes ☐ No ☐ NA	
24. Benefit to local communities ☐ Yes ☐ No ☐ NA	
25. Sharing of study results ☐ Yes ☐ No ☐ NA	
26. Are blood/tissue samples sent abroad ☐ Yes ☐ No ☐ NA	

B. RECOMMENDATION

DECISION	☐ Approval	☐ Minor Revision
	☐ Major Revision	☐ Disapproval
Comments (Identify items for revision)		
Reviewer's Name		Date:
Signature :		

FORM 2.4

INFORMED CONSENT EVALUATION FORM

NCH-IRB Protocol No.		Date:	
Protocol Title:			
Principal Investigators:			

A. INFORMED CONSENT DOCUMENT REVIEW	COMMENTS/ WHAT SHOULD BE IMPROVED?
1. Does the Informed Consent document state that the procedures are primarily intended for research? ☐ Yes ☐ No	
2. Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	
3. Does the Informed Consent document contain comprehensive and relevant information? ☐ Complete ☐ Incomplete	
4. Is the information provided in the protocol consistent with those in the consent form? ☐ Consistent ☐ Inconsistent	
5. Are study related risks mentioned in the consent form? ☐ Complete ☐ Incomplete	
6. Is the language in the Informed Consent document understandable? ☐ Clear ☐ Unclear	
7. Is the Informed Consent translated into the local language/dialect? ☐ Yes ☐ No	

	COMMENTS/ WHAT SHOULD BE IMPROVED?
8. Are there vulnerable participants? ☐ Yes ☐ No	
9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants? ☐ Complete ☐ Incomplete	
10. Are names and contact numbers from the research team and the REC in the informed consent? ☐ Yes ☐ No	
11. Does the ICF provide privacy & confidentiality protection? ☐ Yes ☐ No	
12. Is there any undue inducement for participation? ☐ Yes ☐ No	
13. Is there provision for medical / psychosocial support? ☐ Appropriate ☐ Inappropriate	
14. Is there provision for treatment of study-related injuries ☐ Appropriate ☐ Inappropriate	
15. Is the amount paid to participants stated? ☐ Appropriate ☐ Inappropriate	

B. RECOMMENDATION

DECISION :	☐ Approval	☐ Minor Revision		
	☐ Major Revision	☐ Disapproval		
Comments (Identify items for revision)				
Reviewer's Name		Date:		
Signature :				

FORM 2.5

NCH-IRB NOTICE FOR PROTOCOL MODIFICATION
(for Initial and Continuing Review)

To be filled up by NCH-IRB Secretariat

Date _____

To: (Name of PI) _____

Contact No.

Protocol Title

NCH-IRB Protocol No./		Version Date:	
ICF Version No./		Version Date:	

Type of Submission

☐	Initial Review	☐	Resubmission
☐	Amendment	☐	Progress Report
☐	Final Report	☐	Others

This is to inform you of the NCH-IRB decision related to the documents you have submitted:

ITEMS FOR REVISION	REVISIONS/INFORMATION REQUIRED FROM THE PRINCIPAL INVESTIGATOR
Protocol	
Informed Consent	
Others	

PLEASE SUBMIT THE REVISED DOCUMENTS WITHIN 15 DAYS FROM RECEIPT OF THIS NOTICE.

Type of review

- ☐ Expedited
- ☐ Full board
- ☐ Exempt

Meeting Date:

NCH-IRB DECISION

- ☐ Approved
- ☐ Minor revisions required
- ☐ Major revisions required
- ☐ More Information Required
- ☐ Others: _____

NCH-IRB Chair Person	Name	Signature	Date

FORM 2.6

CERTIFICATE OF APPROVAL

Date _____

This is to certify that the following protocol and related documents have been granted approval by the **National Children's Hospital-Institutional Review Board** for implementation

NCH-IRB Protocol No.			
Principal Investigator/s		Sponsor *If applicable*	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other documents			
Members of research team			
Study sites			
Type of review	☐ Expedited ☐ Full board Meeting date:	Duration of Approval From (date) To	Frequency of continuing review

NCH-IRB Chair Person	Name	Signature	Date

INVESTIGATOR RESPONSIBILITIES AFTER APPROVAL:

- *Submit document amendments for NCH-IRB approval before implementing them*
- *Submit SAE and SUSAR reports to the NCH-IRB within 7 days*
- *Submit progress report every 6 months*
- *Submit final report after completion of protocol procedures at the study site*
- *Report protocol deviation/ violation*
- *Comply with all relevant international and national guidelines and regulations*
- *Abide by the principles of good clinical practice and ethical research*

Received by: _____

Name _____

Signature _____ Date _____

FORM 2.7

CERTIFICATE OF EXEMPTION FROM ETHICS REVIEW

This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the **National Children's Hospital-Institutional Review Board** for implementation

NCH-IRB Protocol No.			
Principal Investigator/s		Sponsor *If applicable*	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other documents			

NCH-IRB Chair Person	Name	Signature	Date

Received by: _____

Name _____

Signature _____ Date _____

FORM 2.8

PROTOCOL RESUBMISSION FORM

To be filled by investigator

NCH-IRB Protocol Number:		Submission Date:	
Protocol Title:			

Document to be revised	☐	Protocol	☐	Informed Consent
	☐	Advertisement	☐	Composition of Research Team
	☐	Others: _____		

Study Duration			
Sponsor:			
Principal Investigator:			
Telephone number:		Fax :	
E-mail:		Preferred means of contact	☐ Phone ☐ Fax ☐ Email
Institution			

NCH-IRB Recommendations	Revisions made by the PI

PI SIGNATURE: _____ **DATE:** _____

RECEIVED BY NCH-IRB SECRETARIAT: _____ DATE: _____