Monitoring Procedures Form

Form 3.1 Protocol Amendment Application Form

Form 3.2 Progress Report

Form 3.3 Closure/Final Report

Form 3.4 Onsite Serious Adverse Event Report

Form 3.5 Protocol Violation/Deviation Report

Form 3.6 Query/Complaint Record

Form 3.7 Study Visit Site Report

Form 3.8 Early Study Termination Application

FORM 3.1

PROTOCOL AMENDMENT APPLICATION FORM

Date of submission	NCH-IRB Protocol No.	Email/ Mobile No.

Principal Investigator	Sponsor

Title of Study	

Study Site	Date of Initial Approval

Items to be Amended	List of Amendments	Reasons

Signature of PI		Date:

FOR NCH-IRB USE

Assessment by Primary Reviewers	**Type of amendments: Minor ___ Major ___** **Does the amendment increase the risks to participants? Yes ___ No ___** **Does the amendment increase the benefits to participants? Yes ___ No ___** **Is there favourable benefit/ risk ratio? Yes ___ No ___** **Comments:**

Recommendations
- ☐ Approve
- ☐ Request further information / modification
- ☐ Others:

Type of review:
- ☐ For Expedited review
- ☐ For Full board review

Reviewer's Name		Signature	Date:	

Received by NCH-IRB Secretariat: (Name/Signature)

NCH-IRB Final Decision:	

Name of NCH-IRB Chair	Signature	Date

FORM 3.2

PROGRESS REPORT

(To be filled up by the Principal Investigator)

NCH-IRB Protocol No.		Initial Approval Date	
Protocol Title			
Investigator.		Sponsor *If applicable*	

Any amendment since the last review? (Describe briefly.)	☐ No	☐ Yes
Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes.)	☐ No	☐ Yes
Any change in the Informed Consent process or documentation since the last review? (Please explain.)	☐ No	☐ Yes
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Summarize)	☐ No	☐ Yes
Any unexpected complication or side effect noted since the last review?(Summarize)	☐ No	☐ Yes
Were there protocol deviation/ violation reports? Summarize What corrective actions were taken?	☐ No	☐ Yes
Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.)	☐ No	☐ Yes

Summary of recruitment:

- ☐ Accrual ceiling set by NCH-IRB
- ☐ New participants accrued since last review
- ☐ Total participants accrued since protocol began

- ☐ No. of participants who are lost to follow up
- ☐ No. of participants withdrawn from the study
- ☐ No. of participants who experienced SAEs/ SUSARs

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.	☐ No	☐ Yes

For NCH-IRB USE

Comments of Primary Reviewer

Name of Primary Reviewer		Date Received	

Assessment by the Primary Reviewer:

	Yes	No	Comments
Do the risks to the study participants remain reasonable in relation to anticipated benefits?			
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent?			
Is there need to revise the ICF?			
Is there need to re-consent subjects enrolled in the study?			
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety?			
Are there concerns about patient safety, inability to comply with the protocol, high dropout rate that affect study implementation?			

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol deviation/ violation, etc.) submitted by the PI

Recommended Action:

_____ Approve
_____ Request further information, specify
_____ Recommend further action, specify
_____ (e.g. Require protocol/ ICF amendment, re-consent) to address concerns about patient safety)

Other Comments:

Primary Reviewer:	Signature:	Date:

FORM 3.3

CLOSURE / FINAL REPORT

NCH-IRB PROTOCOL CODE NO.:		
PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		
PROTOCOL (INITIAL)APPROVAL DATE: <dd/mm/yyyy>		
Email:	**Telephone:**	**Mobile:**
STUDY SITE: <Name and address>		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**

1. Study Arms:

2. Summary of recruitment:

- ☐ Accrual ceiling set by NCH-IRB
- ☐ New participants accrued since last review
- ☐ Total number of participants accrued since protocol began
- ☐ No. of participants who are lost to follow up
- ☐ No. of participants withdrawn from the study
- ☐ No. of participants who experienced SAEs/ SUSARs

Number of participants who completed the study: _____

3. Amendments to the original protocol (including dates of approval):
4. Summary of onsite SAEs reported:
5. Summary of participants' complaints or grievances documented regarding conduct of study:
6. Summary of benefits to participants:
7. Summary of indemnifications of study related injury (If Applicable):
8. If terminated early, specify reason for termination:
9. Progress reports submitted (with dates of approval):
10. Duration of the study (months):
11. Informed consent form used (with version no./date) and attach most recent version:
12. Study objectives and summary of results:

DATE OF LAST REVIEW:
SIGNATURE OF PI:
DATE:
RECEIVED BY: (name of NCH-IRB Staff)
REPORT SUBMISSION DATE: (to be filled out by the NCH-IRB)

NCH-IRB USE

COMMENTS OF PRIMARY REVIEWER (i.e. compliance with the terms of the approved protocol including post-approval review requirements, and overall assessment of risks against benefits in the conduct of study)
RECOMMENDED ACTION: ☐ APPROVE ☐ REQUEST INFORMATION: (specify) ☐ RECOMMEND FURTHER ACTION: (specify) ☐ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE
PRIMARY REVIEWER Signature _____ Date: Name <Title, Name, Surname>

FORM 3.4

ON SITE SERIOUS ADVERSE EVENT REPORT

Whenever there is any SAE event in any research approved by the **National Children's Hospital-Institutional Review Board**, it has to be reported by the principal investigator (PI) to the IRB.

SECTION 1

Principal Investigator:	
Study Title:	Protocol No.:
Name of the study medicine/device:	Report Date: ☐ Initial ☐ Follow-up Onset Date:
Sponsor:	Date of first use:
Title of the Report	Date of the report

Subject's I nitial/number: _____ Age: _____ ☐ Male ☐ Female

Subject's history:	Laboratory findings:
SAE:	Treatment: Outcome: ☐ Resolved ☐ On-going

Seriousness:

☐ Death ☐ Life Threatening

☐ Hospitalization:

☐ Initial ☐ Prolonged

☐ Disability/Incapacity

☐ Congenital Anomaly

☐ Others

Relation to

☐ Drug ☐ Device ☐ Study

☐ Not related

☐ Possibly

☐ Probably

☐ Definitely related

☐ Unknown

Note: PI should attach standard SAE report form(CIOM) to this IRB form.

FOR NCH-IRB USE

Received by:

Name (NCH-IRB Secretariat)	Signature	Date

Reviewer's Comments/ Recommendations

Reviewer's Name:	Signature	Date

Changes to the protocol recommended? ☐ No ☐ Yes
Comments:

Changes to the informed consent form recommended? ☐ No ☐ Yes
Comments:

Recommendation

Name of Reviewer	Signature	Date

TO BE FILLED UP BY THE SECRETARIAT

NCH-IRB Final Action:

- ☐ Request an amendment to the protocol or the consent form
- ☐ Request further information
- ☐ Suspend enrollment of new research participants
- ☐ Suspend all trial-related procedures
- ☐ Termination of the Study
- ☐ Take note and continue monitoring
- ☐ Conduct Study Site Visit
- ☐ Others:

_____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting:_____

FORM 3.5

PROTOCOL VIOLATION/DEVIATION REPORT

NCH-IRB Protocol No.	Date of Submission

Study Title:			
Investigator		Contact No.:	
Sponsor:		Contact No.:	
Reported by		Contact No.:	
Description:			

FOR NCH-IRB PRIMARY REVIEWER'S ASSESSMENT

	PI Deviation from the Protocol	Participant Non-Compliance Recommendation :	
	Major		Noted (no further action needed)
	Minor		Corrective action required
			Site visit needed

Date of full board meeting	
NCH-IRB Decision:	
Required corrective action	

Recorded by NCH-IRB Secretariat	Received by PI
Name/ Signature	Name/ Signature
Date:	Date:

FORM 3.6

QUERY/COMPLAINT RECORD

Date received:		Received by	

Request from :

- ☐ Telephone call Number _____
- ☐ Fax Number _____
- ☐ Mailed letter / Date _____
- ☐ E-mail / Date _____
- ☐ Walk-in/Date/Time _____
- ☐ Others, specify _____

Participant's Name:			
Contact Address:		Phone:	
NCH-IRB Protocol No.:			
Title of the Participating Study/			
Starting date of participation :			
What are requested?			
Action taken:			
Outcome:			

FORM 3.7

STUDY SITE VISIT REPORT

NCH-IRB Protocol No.		Date of the Visit:	
Study Title:			
Principal Investigator:		Phone:	
Sponsor		Site	
Reason for site visit		Persons interviewed	
Total number of expected subjects:		Total subjects enrolled:	

	Yes	No	Comments
Are site facilities appropriate?			
Is confidentiality of documents maintained (e.g. cabinets with lock and keys)?			
Are the test articles properly kept and maintained?			
Are Informed Consent Forms complete?			
Are approved ICF versions used?			
Are copies of the approved versions of the protocol documents kept in the site?			
Are files of all communication with the NCH-IRB found in the site?			
Does the site keep copies of all communication with the NCH-IRB in the site?			
Are copies of adverse event reports kept?			
Are Investigator functions properly delegated to qualified research personnel?			
Is there appropriate documentation of qualifications of personnel?			
Are all Case Record Forms up to date?			
Are copies of protocol deviation/ violation reports kept in the site?			
Is there evidence of appropriate corrective action taken as recommended by the NCH-IRB?			

Summary of findings:
Recommendations:

Duration of visit: (hours)		Starting from:		Finish:	
Names of NCH-IRB Member Visitors:					
Report prepared by:		Date:			
Signature					

FORM 3.8

EARLY STUDY TERMINATION APPLICATION

NCH-IRB Protocol No:			
Protocol Title:			
Principal Investigator:			
Phone :		E-Mail:.	
Department:			
Sponsor:			
NCH-IRB Approval Date:		Date of Last Report:	
Starting Date:		Termination Date:	
No. of Participants:		No. Enrolled:	
Reason for early termination Summary of Results			
Accrual Data: How many have completed the study? How many are still active? Plans for those who are still active in the study			
P.I. Signature:		Date:	

FOR NCH-IRB USE

Assessment by the Primary Reviewer (any issue related to participant safety?)

Recommendations	
Final NCH-IRB decision	
Date of full board meeting	