



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

**EFFECTIVE DATE:
10/01/2018**

Documentation and Archiving Forms

Form 4.1 Meeting Agenda Template

Form 4.2 Meeting Minutes Template

Form 4.3 Request to Access IRB Files



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

EFFECTIVE DATE:
10/01/2018

FORM 4.1

MEETING AGENDA TEMPLATE

National Children's Hospital–Institutional Review Board

Address

Telephone

(Date)

NOTICE OF MEETING

To : National Children's Hospital–IRB Members:

(NAME OF IRB MEMBER 1)

(NAME OF IRB MEMBER 2)

(NAME OF IRB MEMBER 3)

(NAME OF IRB MEMBER 4)

(NAME OF IRB MEMBER 5)

(NAME OF IRB MEMBER 6)

(NAME OF IRB MEMBER 7)

(NAME OF IRB MEMBER 8)

(NAME OF IRB MEMBER 9)

DATE OF MEETING:

TIME OF MEETING:

VENUE OF MEETING:

AGENDA:

I. PROTOCOL REVIEW

(Note: All protocols for review should include the following information: Protocol No., Title, PI, Sponsor, Reviewers)

1. New Protocols
2. Resubmitted Protocols
3. Protocol for Clarification
4. Protocol Amendments
5. Progress Reports
6. Final Reports



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

EFFECTIVE DATE:
10/01/2018

7. Protocol Deviation/Violation
8. Early Study Termination
9. Site Visit Reports
10. Onsite SAE Reports
11. Expedited Review Report (includes all protocols reviewed through expedited means)

II. OTHER MATTERS:

RSVP: Name of Staff (Mobile number)

Prepared by:

(Name of IRB Member–Secretary)

Chair, NCH–IRB



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

EFFECTIVE DATE:
10/01/2018

FORM 4.2

MEETING MINUTES TEMPLATE

National Children's Hospital–Institutional Review Board

Minutes of the Meeting

(Date), (Venue), (Time)

1. ATTENDANCE

PRESENT:

- 1)
- 2)
- 3)
- 4)
- 5)

ABSENT:

- 1)
- 2)

2. CALL TO ORDER

3. DETERMINATION OF QUORUM

4. DISCLOSURE OF CONFLICT OF INTEREST (COI)

5. APPROVAL OF THE MEETING AGENDA

6. APPROVAL OF THE MINUTES LAST MEETING

7. BUSINESS ARISING FROM THE MINUTES

8. PROTOCOL REVIEW

8.1. New Protocols

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Primary reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of interest	



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

EFFECTIVE DATE:
10/01/2018

- A. Protocol Assessment: Led by medical/ scientific reviewer
 - 1. Discussion of technical issues
 - 2. Discussion of ethical issues
 - 3. Decision by voting (Indicate voting results)
- B. Discussion of Informed Consent
 - 1. Ethical issues
 - a. Recruitment and Screening
 - b. Patient Information Sheet
 - c. Informed Consent Form
 - d. Assent Forms, if appropriate

Summary of Recommendations

Decision: *(Indicate voting results)*

- 1. Approval
- 2. Minor Modification
- 3. Major Modification
- 4. Disapproval (reasons to be stated)

Duration of Approval

Frequency of continuing
review (in case of approval)

1.1. PROTOCOLS FOR MODIFICATIONS

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of PI response to initial review	
Recommendations	
Decision <i>(indicate voting results)</i>	



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

**EFFECTIVE DATE:
10/01/2018**

Approval expiration date	
Frequency of continuing review (in case of approval)	

1.2. PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	
Amendment Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of amendment requested	
Recommendations	
Decision <i>(indicate voting results)</i>	(Approval, Major Modification, Minor Modification, Disapproval)

1.3. PROGRESS REPORT

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of progress reported	
Recommendations	
Decision	



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

**EFFECTIVE DATE:
10/01/2018**

1.4. FINAL REPORTS

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of final report	
Recommendations	
Decision	

1.5. PROTOCOL DEVIATIONS

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Deviation Report	
Recommendations	
Decision	



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

EFFECTIVE DATE:
10/01/2018

1.6. EARLY STUDY TERMINATION

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of early termination	
Recommendations	
Decision	

1.7. SITE VISIT REPORTS

Protocol Code	
Protocol Approval Date	
Site Visit Date	
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Site Visit Report	
Recommendations	
Decision	(No further action, Request information, Recommend corrective action)

1.8. ON SITE SAE/REPORTS

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

**EFFECTIVE DATE:
10/01/2018**

Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of SAE/ SUSAR reports	

APPENDICES

REPORT OF RESULTS OF EXPEDITED REVIEW

1. NEW PROTOCOLS (MINOR RISKS)

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Decision	Approval

2. PROTOCOLS FOR MINOR REVISION

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

3. MINOR PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	
Date of Amendment Submission	
Protocol Title	



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

**EFFECTIVE DATE:
10/01/2018**

Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

4. OTHER MATTERS

5. ADJOURNMENT

Prepared by:

Approved by:

Signature over Name
NCH-IRB Member-Secretary
Date:

Signature over Name
NCH-IRB Chair
Date:

Other Forms: Approval Letter
Notification Letters (for the different post-approval Submissions)



NATIONAL CHILDREN'S HOSPITAL

Appendix D

VERSION NO: 4

EFFECTIVE DATE:
10/01/2018

FORM 4.3

REQUEST TO ACCESS REC FILES

I, (Name, Surname) as a non-member of the NCH-IRB, understand that the documents I am given access to by NCH-IRB are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate, give or distribute these documents to any person(s) without permission from the NCH-IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Requested document	
Reason for request	
Number of copies requested	

RECIPIENT

Date: <dd/mm/yyyy>

Signature _____

Name <Title, Name, Surname>

NCH-IRB

MEMBER-SECRETARY

Date: <dd/mm/yyyy>

Signature _____

Name <Title, Name, Surname>