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APPENDIX A
IRBREC Structure and Composition Forms

- Form 1.1 Statement of Responsibilities of **NCH-IRBREC Member, Alternate member and Independent Consultant**
- Form 1.2 Curriculum Vitae Form
- Form 1.3 Confidentiality and Conflict of Interest Agreement
- Form 1.4 Training Record of an **NCH-IRBREC Member**
- Form 1.5 Invitation to Independent Consultants

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FORM 1.1

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STATEMENT OF RESPONSIBILITIES OF NCH-IRB MEMBER AND ALTERNATE MEMBER
(To be attached to appointment document from the Hospital)

FORM 1.1

(Date)Date

Dear (Name of NCH-IRB Member and Alternate Member)

As an appointed member and Alternate member of the NCH-IRB, you will have the following roles and responsibilities:

- Serve as Primary Reviewer for research protocol documents within your area of expertise, and as General Reviewer for all researches discussed at convened meetings of the NCH-IRB
- Submit on time to the Secretariat the completed Protocol and ICF Assessment forms when designated as Primary Reviewer
- Conduct expedited review on behalf of the NCH-IRB of protocols assigned by the Chair/Member-Secretary and submit the assessment forms on time.
- Perform post-approval review procedures of protocol-related documents within 7 calendar days
- Update CV and training record every time appointment is renewed
- Conform at all times with the legal and ethical principles accepted by the NCH-IRB
- Attend basic and continuing education on Research Ethics at least once a year
- Perform other tasks assigned by the NCH-IRB Chair.

If you agree with the terms of this appointment, please sign on the space below, and return one copy to the NCH-IRB Secretariat. Submit duly-signed updated Curriculum Vitae and the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

(Print name and sign)

Chair
NCH-IRB

Conforme:



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(Print name and sign) (Date)

Statement of Responsibilities of NCH-IRBREC Member *To be attached to appointment document from the Hospital*

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Date

Dear (Name of NCH-IRBREC Member)

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As an appointed member of the (Name of Hospital)NCH-IRB-REC you will have the following roles and responsibilities*:

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- Serve as Primary Reviewers for research protocol documents within your/their area of expertise, and as General Reviewers for all researches discussed at convened meetings of the NCH-IRBREC
- Submit on time (within 7 calendar days) to the Secretariat the completed Protocol and ICF Assessment forms when they are designated as Primary Reviewers
- Conduct expedited review on behalf of the NCH-IRB-REC of protocols assigned by the REC Chair/Member Secretary and submit the assessment forms on time (within 7 calendar days)
- Perform post-approval review procedures of protocol-related documents within 7 calendar days
- Update CV and training record every time appointment is renewed
- Conform at all times with the legal and ethical principles accepted by the NCH-IRBREC
- Attend basic and continuing education on Research Ethics at least once a year
- Perform other tasks assigned by the REC Chair.

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If you agree with the terms of this appointment, please sign on the space below, and return one copy to the (Name of Hospital)NATIONAL CHILDREN'S HOSPITAL-IRB-REC Secretariat. Submit duly signed updated Curriculum Vitae and the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

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REC Chair
(Name of Hospital)NATIONAL CHILDREN'S HOSPITAL-IRB

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Conforme:

(Print name and sign)

Date

FORM 1.2

CURRICULUM VITAE OF NCH-IRBREC MEMBER

CURRICULUM VITAE OF NCH-IRB MEMBER

Last name	<input type="text"/>	First name	<input type="text"/>
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Position in the the	<input type="text"/>	Address	<input type="text"/>
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Date of Appointment	<input type="text"/>	Contact No.	<input type="text"/>
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Education	<input type="text"/>
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Research and Ethics Training/s:	<input type="text"/>
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WORK EXPERIENCE

Occupation	<input type="text"/>
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FORM 1.3

CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT

To be filled up by all ~~NCH-IRB REC~~ Members and Staff

Previous work experience

Present work experience

Research-related Experience

Know all Men by these Presents:

In view of the appointment of (TITLE NAME INSTITUTIONAL AFFILIATION), as a member of the (~~Name of Hospital~~)NATIONAL CHILDREN'S HOSPITAL~~NCH-IRB-REC~~, and hereinafter referred to as the *Undersigned*, and

Whereas:

the *Undersigned* has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

the appointment of the *Undersigned* as a member of the NCH-IRB (~~Name of Hospital~~)NATIONAL CHILDREN'S HOSPITAL-IRB-REC 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;



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the fundamental duty of an [NCH-IRBREC](#) 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 thereof under review; and

the [NCH-IRB \(Name of Hospital\) NATIONAL CHILDREN'S HOSPITAL-IRB REC](#) 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 following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed [IRBREC](#) member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the [IRBREC](#) to carry out its mandate.

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Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the *Undersigned* in conjunction with and/or in the course of the performance of his/her duties as a member/Independent Consultant of the [NCH-IRB \(Name of Hospital\) NATIONAL CHILDREN'S HOSPITAL-IRB REC](#).

Any written information provided to the *Undersigned* that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the [NCH-IRBREC](#).

As such, the *Undersigned* agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"). Moreover, the *Undersigned*



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agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The **Undersigned** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the **Undersigned** confirms that his/her performance of this agreement is consistent with NCH-IRB (Name of Hospital) NATIONAL CHILDREN'S HOSPITAL's policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the NCH-IRBREC to manage these conflicts of interest (conflict issues), if any, in such a way that the ultimate outcome of the protection of human subjects remains.

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It is the policy of the NCH-IRBREC that no member/consultant 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 NCH-IRBREC.

The **Undersigned** will immediately disclose to the Chair of the NCH-IRB (Name of Hospital) NATIONAL CHILDREN'S HOSPITAL-IRB-REC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the NCH-IRBREC, and to abstain from any participation in discussions or recommendations in respect of such proposals.

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If an applicant submitting a protocol believes that an NCH-IRBREC 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 Chair. The request must contain evidence that substantiates the claim that a conflict exists with the NCH-IRBREC member(s) in question. The NCH-IRBREC may elect to investigate the applicant's claim of the potential conflict.



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When a member/consultant has a conflict of interest, the member should notify the Chairperson and may not participate in the NCH-IRB/IRB REC review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

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

Agreement on Confidentiality and Conflict of Interest

[To the Undersigned: Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (*signed and dated Agreement*) will be kept on file in the custody of the NCH-IRB (Name of Hospital) NATIONAL CHILDREN'S HOSPITAL-IRB REC. A copy will be given to you for your records.]

In the course of my activities as a member of the NCH-IRB (Name of Hospital) NATIONAL CHILDREN'S HOSPITAL-IRB REC, I will 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, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Board'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 Board duties) to the Chair upon termination of my functions as an NCH-IRB/IRB REC member.

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

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



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Title/Name

Date

NCH-IRB Chair

Date

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Title/Name

Date

(Name of Hospital) NATIONAL CHILDREN'S HOSPITAL - IRB
REC Chair

Date



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FORM 1.4

TRAINING RECORD OF AN NCH-IRBREC MEMBER

(To be summarized by NCH-IRBREC Staff and checked by NCH-IRBREC Member)

Last name		First name	
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BASIC COURSES	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. GCP Training				
2. Research Ethics				
3. REC Standard Operating Procedures (SOP)				

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CONTINUING ETHICS EDUCATION : Research Ethics Workshops, Conferences, Meetings, Lectures	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1.				
2.				
3.				
4.				
5.				

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FORM 1-5
INVITATION TO INDEPENDENT CONSULTANTS

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To be attached to appointment document from the Hospital

FORM 1.5

INVITATION TO INDEPENDENT CONSULTANTS

(To be attached to appointment document from the Hospital)

(Name of Independent Consultant)
(Institution)

Date

Dear _____

(Name of Independent Consultant)
(Institution)

(Date)

Dear (Name of NCH-IRB Member and Alternate Member)

Date

Dear _____

We hereby invite you to serve as Independent Consultant for the following protocol:

<u>Protocol Code</u>	
<u>Protocol Title</u>	
<u>Principal Investigator</u>	
<u>Primary Reviewers</u>	
<u>Sponsor/CRO</u>	

Please review the technical and ethical issues in the protocol based on the assessment forms that we hereby attach. Please forward your assessment/comments to the Secretariat within 7 days. Please attend the full board meeting on _____ at _____.

Thank you for your support and cooperation.

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If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the NCH-IRB Secretariat. Please sign, date and submit your latest Curriculum Vitae and the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

(Print name and sign)

Chair
NCH-IRB
Chair
NCH-IRB

Conforme: _____

(Print name and sign) (Date)

We hereby invite you to serve as Independent Consultant for the following protocol:

(Title of Protocol), (Protocol Number), (Name of PI), (Sponsor)

Please review the technical and ethical issues in the protocol based on the assessment forms that we hereby attach. Please forward your assessment/ comments to the Secretariat within 7 days. Please attend the full board meeting on _____ at _____.

Thank you for your support and cooperation.

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the ~~(Name of Hospital)~~ NATIONAL CHILDREN'S HOSPITAL-IRB REC Secretariat. Please sign, date and submit your latest Geurriculum Vitae and the Confidentiality and Conflict of Interest Agreement.

Very truly
yours,

IRBREC Chair
(Name of
Hospital) NATIONAL

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CHILDREN'S HOSPITAL

Conforme:

(Print name
and sign)

Date

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