



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

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|----------------|--|
| Supersedes: | Previous NCH-IRB SOPs |
| Prepared by: | 2017 NCH-IRB SOP Committee |
| Reviewed by: | NATIONAL CHILDREN'S HOSPITAL INSTITUTIONAL REVIEW BOARD (NCH-IRB) |
| Approved by: | EPIFANIA S. SIMBUL, MD, FPPS, CEO VI Medical Center Chief II |
| Approval Date: | |

1. STRUCTURE AND COMPOSITION

- 1.1 Appointment, Roles and Responsibilities of NCH-IRB Members and Alternate Members
- 1.2 Appointment of Independent Consultants
- 1.3 Training of NCH-IRB Members and Staff

See Appendix A

Form 1.1 Statement of Responsibilities of NCH-IRB 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-IRB Member

Form 1.5 Invitation to Independent Consultants



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

1.1. APPOINTMENT OF NATIONAL CHILDREN'S HOSPITAL-INSTITUTIONAL REVIEW BOARD (NCH-IRB) MEMBERS AND ALTERNATE MEMBERS

1.1.1. Purpose

To describe the appointment procedures of the members and alternate members of the NCH-IRB and to identify the roles and responsibilities of NCH-IRB officers, members and alternate members.

1.1.2. Scope

While the NCH-IRB remains under the authority of the Medical Center Chief II, it has to maintain its independence and to develop its competence related to decision making as defined in international and national guidelines. The membership's SOPs cover the nomination and appointment procedures of NCH-IRB members, alternate members and officers.

1.1.3. Responsibility

It is the responsibility of the Medical Center Chief II to formally appoint the members, alternate members and officers of the NCH-IRB after due consultation with the current members of the NCH-IRB.

1.1.4. Process Flow/Steps

| NO. | ACTIVITY | PERSON/S RESPONSIBLE | TIMELINE |
|-----|--|--|---|
| 1 | Define the composition of the membership of the NCH-IRB | Chair, Member-Secretary, Members | To be done 60 days before expiry of appointment |
| 2 | Open the nomination of new NCH-IRB members from NCH-IRB itself, hospital management, department chairs, section heads and submit names of potential members to the NCH-IRB members for screening | NCH-IRB Members, Hospital Management, Department Chairs, Section Heads | |
| 3 | Recommend and submit the list of potential members to the Medical Center Chief II | Chair | |
| 4 | Appoint NCH-IRB members, alternate members and officers | Medical Center Chief II | |
| 5 | Ensure completion of membership documents | New Member, Secretariat | |
| 6 | Organize and complete the documents in the Membership Files | Staff | |



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

1.1.5. Detailed Instructions

1.1.5.1. Define the composition of the membership of the NCH-IRB

- The Chair discusses the qualifications of additional/new members with the existing members of the NCH-IRB.
- The NCH-IRB shall be composed of at least 9 members.
- Its membership shall be multidisciplinary. The NCH-IRB members should have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by its own affiliated and non-affiliated researchers.
 - The membership shall include persons whose primary concerns are in medical science and/or public health, with at least one member who is in a non-medical/non-scientific area, and at least one member who is not affiliated with National Children's Hospital.
 - Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the NCH-IRB should include a person who will represent the interest and concerns of the community.
 - The NCH-IRB shall aim for adequate representation of men and women members in order to promote gender sensitivity in its review procedures.
 - The NCH-IRB shall have representatives from both the older and younger generations.
 - During review meetings, the NCH-IRB shall adhere to quorum requirements as defined in international and national guidelines for RECs that review health research. When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist shall be present during its board meeting. (*Refer to SOP No. 4 on Conduct of Review Meeting*)

1.1.5.2. Open the nomination of new NCH-IRB members and alternate members from NCH-IRB itself, hospital management, department chairs, section heads and submit names of potential members to the NCH-IRB members for screening

- Make an oral announcement of the open nomination process for the NCH-IRB to hospital management, department chairs, and section heads during regular monthly hospital assembly.



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

- Any hospital staff, upon the recommendation of his/her section head, may submit the name of the nominees to the Chair for deliberation, with their corresponding Curriculum Vitae.
- Members and alternate members are selected based on their good moral character and personal capacities, their scientific expertise and knowledge of ethical principles, as well as their willingness to volunteer their time and effort to perform their functions in the NCH-IRB.
- Members and alternate members shall have prior training in research ethics, research methodology, and Good Clinical Practice or should be willing to undergo continuing training during their membership.
- During the NCH-IRB meeting, the Chair presents the credentials of the person being nominated. The NCH-IRB Members discuss and decide by consensus, and in the absence of consensus, by majority vote, on the final list of nominees to be submitted to the Medical Center Chief II. Conflict of interest issues of nominees shall also be discussed.
- Members are medical/scientific (doctors), nonmedical/scientific (nurses with Master's or Doctorate degree), nonmedical/non-scientific (lay member, nurse)
- Members are either institutional/affiliated (NCH employee or visiting consultant at NCH) or non-institutional/non-affiliated (not employee of NCH and not a visiting consultant at NCH)

1.1.5.3. Recommend and submit the list of potential members to the Medical Center Chief II

a. Selecting Members and Alternate members

- The Medical Center Chief II reviews the list of nominees, their credentials and decides on the appointment to be made.
- The appointment letter should include conditions of appointment, term of office, and honorarium (if any), as follows:
 - Members/alternate members are appointed for a period of three (3) years and renewable for several consecutive terms depending on their performance.
 - Willingness to make public his/her full name, profession, and affiliation as an NCH-IRB member
 - Members/alternate members shall disclose all financial accountability related to their work in the NCH-IRB and publicly disclose its financial records upon request
 - Members/alternate members shall sign the Confidentiality and Conflict of Interest Agreement. The agreement should cover all applications, meeting, deliberations, information on research participants and related matters.



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

- It should contain an attachment about the responsibilities of an NCH-IRB member, as follows:
 - Serve as Primary Reviewer for research protocol documents within their area of expertise, and as General Reviewer for all researches discussed at convened meetings of the NCH-IRB
 - 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 of protocols assigned by the NCH-IRB Chair 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 (newly appointed or renewed).
 - Conform at all times with the legal and ethical principles accepted by the NCH-IRB
 - Attend SOP workshop.
 - Attend continuing education Research Ethics. This includes in-house training/workshop/lecture and Convention/Annual assembly.
 - Attend GCP training every three years
 - Perform other tasks requested by the NCH-IRB Chair.

- It should contain an attachment about the responsibilities of an NCH-IRB alternate member, as follows:
 - **Assumes the responsibilities of the member he/she represents**

- Appointment of Non-Medical/Non-Scientific Member of the NCH-IRB should contain an attachment of their responsibilities as follows:
 - The non-medical or non-scientific members of the NCH-IRB shall focus on the human subject/participant concerns and review the informed consent process and the informed consent forms to ensure adequate application of international and national principles and guidelines.

- The NCH-IRB shall adopt some mechanisms to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity, as well as the development and maintenance of expertise.



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

b. Selecting Officers

The NCH-IRB Chair, Member-Secretary are nominated by the members of the NCH-IRB. They should be highly-respected individuals within or outside the institution, fully capable of managing the NCH-IRB and ensuring fairness and impartiality in dealing with matters brought to NCH-IRB. They should have the following qualifications:

- Good personal characteristics and reputation
- Have training on Basic Research Ethics, GCP in Research and advanced courses on Research Ethics in the past 3 years
- Have been a member of an Ethics Review Committee for at least 3 years.

1.1.5.4. Appoint NCH-IRB members and officers

- The Medical Center Chief II of the National Children's Hospital is responsible for appointing the NCH-IRB Officers with due consideration to the NCH-IRB recommendations.
- The Medical Center Chief II issues an appointment letter that identifies the NCH-IRB Officers
- The appointment letter should include an attachment of the responsibilities of the NCH-IRB Officers as follows:

Responsibilities of the Chair

The responsibilities of the Chair include the following:

- Ensures that all NCH-IRB members receive orientation and undergo basic Research Ethics Training immediately after their appointment, and continuing education thereafter
- Obtains administrative and logistics support for the sustained operations of the NCH-IRB
- Approves the agenda and presides over NCH-IRB review meetings (*If Chair has COI relative to the protocol for deliberation she/he designates the Member Secretary to preside over the meeting. If both have COI, the Chair designates another member to preside over the meeting*)
- Selects suitable (*somebody with related expertise*) member/independent consultant to be the primary reviewer of a protocol whether by full board or expedited review, and ensures that aforementioned member does not have conflict of interest
- Manages complaints from study participants, authorities or the general public
- Designates a member or group of members to investigate in cases of complaints or reports of major non-compliance.



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

- Ensures that the NCH-IRB is perceived as fair and impartial, and complies with institutional, national and international standards
- Represents the NCH-IRB in various local, national and international meetings and conferences.
 - Prepares the Annual Work Financial Plan (WFP) and the Project Procurement Management Plan (PPMP) and for approval by the Medical Center Chief II
 - Ensures adherence to quality standards to maintain the accreditation status

Responsibilities of the Member-Secretary

The responsibilities of the Member-Secretary include the following:

- Assumes the position of the Chair in his/her absence
- Supervises the NCH-IRB Staff related to good NCH-IRB office management
- Prepares and finalizes the meeting agenda of full-board meeting after consultation with the Chair
- Collects and reviews the assessment forms submitted by the Primary Reviewers before the meeting
- Ensures that the members completely fill out necessary forms used for the review of protocol or protocol related submissions,
- Supervises the NCH-IRB Staff in the preparation of the meeting agenda and minutes
- Supervises the NCH-IRB Staff in the preparation of the annual report of the IRB to be submitted to the Medical Center Chief II, DOH, PHREB, FERCAP and other regulatory and legal bodies.
- Ensures good NCH-IRB documentation and archiving.
- Ensures overall NCH-IRB compliance with good clinical practice.
- Ensures good financial management of NCH-IRB resources

Responsibilities of the Secretariat

The NCH-IRB secretariat is composed of the Member-Secretary and the administrative staff who are employees of NCH.

The Secretariat shall have the following functions:

- Organizing an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance and distribution of study files



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

- Organizing NCH-IRB meetings regularly
- Preparation and maintenance of meeting agenda and minutes
- Maintaining good NCH-IRB documentation and archiving procedures
- Communicating with the NCH-IRB members and Investigators
- Arrangement of training for personnel and NCH-IRB members
- Organizing the preparation, review, revision and distribution of SOPs and guidelines;
- Providing the necessary administrative support for NCH-IRB-related activities to the Chair of the NCH-IRB
- Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the NCH-IRB members
- Maintaining a library of relevant resource materials and references

1.1.5.5. Ensure completion of membership documents

- After the approval of the appointment, newly appointed members should complete all documents in their Membership File.
- Upon the acceptance of their appointment, and before assuming their responsibilities as member, they shall sign and date the TOR of the appointment letter indicating their willingness to assume their responsibilities.
- The Secretariat provides duplicate copies of the Confidentiality and Conflict of Interest Agreement form (*NCH-IRB Form No. 1.3*) to newly appointed members of the NCH-IRB, one copy for the member and the other to be included in the Membership File. For each protocol that they review, they must disclose their COI (*any interest or involvement such as financial, professional or otherwise in a research proposal under review*).
- The appointee is also required to submit an updated, signed and dated curriculum vitae, and the completed Training Record including photocopies of relevant training certificates.

Resignation, Disqualification, and Replacement of Members

- Members may resign from their positions by submitting a letter of resignation to the Chair and endorsed to the Medical Center Chief II.
- Members may be separated from the committee by disqualification for valid reasons as determined by majority vote of the NCH-IRB members.



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

- Members who have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.
- The terms of replacement shall be limited to the remaining term of the member that he/she has replaced.

1.1.5.6. Organize and complete the documents in the Membership Files

- The Membership Files shall contain the following:
 - Appointment letter signed and dated by the appointee
 - Updated curriculum vitae that is signed and dated by the member
 - The CV is updated every time the appointment is renewed.
 - Training record and photocopy of Training Certificates of relevant trainings
 - Confidentiality and Disclosure of Conflict of Interest Agreement signed and dated by the member.
- The NCH-IRB Staff creates one membership file for each member, and files the following documents in each member's file.
 - Letter of Appointment
 - Curriculum Vitae
 - Training Records
 - Confidentiality and Disclosure of Conflict of Interest Agreement



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

1.2. APPOINTMENT OF INDEPENDENT CONSULTANTS

1.2.1. Purpose

To describe the procedures for the appointment of NCH-IRB independent consultants

1.2.2. Scope

This SOP describes the procedures for engaging the services of a professional/expert as an independent consultant to the NCH-IRB. If the Chair of the NCH-IRB determines that a study involves procedure(s) that are not within the area of competence or expertise of any of the NCH-IRB members, the Chair may invite individuals with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the NCH-IRB.

1.2.3. Responsibility

Upon the advice or recommendation of the Member-Secretary or any NCH-IRB member, the NCH-IRB Chair may recommend the name of the independent consultant to the Medical Center Chief. The Medical Center Chief appoints, upon the recommendation of the NCH-IRB Chair, the independent consultant.

1.2.4. Process Flow/Steps

| NO. | ACTIVITY | PERSON/S RESPONSIBLE | TIMELINE |
|-----|---|----------------------------------|---|
| 1 | Assess the need for Independent Consultant and seek approval for contracting their services | Chair, Member-Secretary, Members | To be done (every quarter) as the need arises |
| 2 | Recommend an Independent Consultant | Chair, Member-Secretary, Members | To be completed within 30 days |
| 3 | Appoint an independent consultant | Medical Center Chief | |
| 4 | Organize and complete the documents in the Independent Consultant's File | Secretariat | |

1.2.5. Detailed Instructions

1.2.5.1. Assess the need for an independent consultant and seek approval for contracting his/her services



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

- Considering the nature of the protocol for review, the Chair with the Members, identify the expertise needed that the NCH-IRB membership may not have.
- The Chair submits the name of the independent consultant to the Medical Center Chief II for appointment and to request for corresponding honorarium.

1.2.5.2. Recommend an independent consultant

- The chair recommends the name of the independent consultant to the Medical Center Chief, who then appoints the independent consultant
- Once the Chair decides to invite an Independent Consultant, the NCH-IRB Secretariat prepares the letter of invitation that includes the following:
 - Terms of Reference (TOR) - duration of consultancy, general overview of deliverables
 - Honorarium
 - Request for a copy of the consultant's curriculum vitae (CV)
- The NCH-IRB Staff sends the letter to the independent consultant after it is signed by the Chair and the Medical Center Chief II together with the duplicate copies of the Confidentiality and Conflict of Interest Agreement form for the consultant's signature.
- The NCH-IRB Staff asks the independent consultant to sign and date his/her acceptance of the TOR of the appointment.
- The NCH-IRB Staff collects the signed and dated Confidentiality and Conflict of Interest Agreement, and the signed and dated updated CV using the prescribed format.

1.2.5.3. Organize and complete the documents in the Independent Consultant's Files

- The Independent Consultant's File shall contain the following:
 - Appointment letter by the Medical Center Chief
 - NCH-IRB Letter of invitation signed and dated by the NCH-IRB Chair
 - Updated curriculum vitae that is signed and dated by the Independent Consultant
 - The CV is updated every time the appointment is renewed.
 - Training record and photocopy of Training Certificates of relevant trainings



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

**EFFECTIVE DATE:
11/01/2018**

- Confidentiality and Disclosure of Conflict of Interest Agreement signed and dated by the Independent Consultant.
- The NCH-IRB Staff creates one file for each independent consultant.



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

1.3. TRAINING OF NCH-IRB MEMBERS AND STAFF

1.3.1. Purpose

To describe NCH-IRB procedures to ensure initial and continuing training of NCH-IRB members and staff

1.3.2. Scope

The NCH-IRB recognizes the importance of training and continuing professional development. This SOP describes the training requirements of NCH-IRB members and staff from initial training to continuing education to maintain and update NCH-IRB competence in the review of different types of protocols.

1.3.3. Responsibility

It is the responsibility of the NCH-IRB officers, alternate members, members and staff to have themselves educated and trained regularly.

It is the responsibility of the NCH-IRB Chair along with the Member-Secretary to assess the training needs and prepare a training plan for all members, Independent Consultants, and staff.

The Secretariat keeps track of the training records of all members, alternate members, Independent Consultants, and staff in accordance with the training plan.

1.3.4. Process Flow/Steps

| NO. | ACTIVITY | PERSON/S RESPONSIBLE | TIMELINE |
|-----|--|-------------------------|--|
| 1 | Require basic research ethics training for all members and staff | Chair | Needs assessment to be done at the beginning of the year |
| 2 | Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses | Chair, Member-Secretary | |
| 3 | Track member and staff participation in initial and continuing ethics training | Chair, Secretariat | |
| 4 | File the certificates of initial and continuing ethics training in the Membership File | Secretariat | |

1.3.5. Detailed instructions

NCH-IRB members should maintain competence by ensuring that they have updated knowledge of the following:



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc.
- International meetings and conferences

1.3.5.1. Require Basic Research Ethics Training for all members and staff

- All NCH-IRB members and alternate members are required to have basic research ethics training that shall consist of research ethics principles, GCP, SOPs, etc. Upon appointment, a new member, alternate member or staff undergoes orientation, individually or as a group, to cover the following:
 - Member's/ Alternate member's/ Staff's responsibilities;
 - Confidentiality and Conflict of Interest Agreement;
 - NCH-IRB review process and use of Protocol and ICF Assessment forms; and
 - NCH-IRB SOPs.
- The NCH-IRB Chair and Member-Secretary shall ensure that initial research ethics training is provided to all new members.

1.3.5.2. Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses

- The NCH-IRB Chair provides training opportunities to members/alternate members/staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.
- The NCH-IRB Chair and Secretariat plan the training activities for individual IRB members/alternate members based on their training needs.
- The NCH-IRB Chair and Secretariat track and facilitate attendance of NCH-IRB members/alternate members and staff of specific training activities needed to ensure that each one gets training at least every two years for GRP and every three years for Continuing Education and GCP.
- The NCH-IRB Members/alternate members who participate in research ethics training course or seminar-workshops either through personal or through NCH-IRB efforts/funding are encouraged to:
 - Share information with other members during NCH-IRB meetings; and



NATIONAL CHILDREN'S HOSPITAL

Structure and Composition

VERSION NO: 4

EFFECTIVE DATE:
11/01/2018

- Distribute photocopies/e-copies of relevant materials to the other members.

1.3.5.3. Track member, alternate member and staff participation in initial and continuing ethics training and file the documents in the Membership File

- For in-house training, the NCH-IRB Staff prepares attendance sheets with relevant information about the topic, duration, date and venue. They ask member-attendees to sign the attendance sheet and keeps a photocopy of the attendance in the membership files, if Training Certificate is not given.
- All NCH-IRB Members, alternate members and Staff should regularly update their Training Record. They should submit proof of attendance in relevant training or continuing professional education sessions conducted outside of the institution – e.g. certificates of training- to the NCH-IRB Staff for filing.
- Administrative Staff should update the Training Record of individual Members, alternate members and Staff to reflect their attendance in training activities every time a photocopy of Training Certificate is submitted for filing.

1.3.5.4. File the certificates of initial and continuing ethics training in the Membership File

The NCH-IRB Secretariat file the certificates of initial and continuing ethics training in the Membership File.