	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD CHH IRB	
Version: 09 Date of Approval: 08/21/24 Date of Effectivity: 08/21/24	**SOP 1.1 SELECTION AND APPOINTMENT OF MEMBERS**	

1. Purpose

To describe the appointment procedures of the members of the CHH IRB and to identify the roles and responsibilities of IRB officers and members.

2. Scope

While the CHH IRB remains under the authority of the Medical Director, it has to maintain its independence and develop its competence related to decision making as defined by the international and national guidelines. The SOP for membership covers the nomination and appointment procedures of the members and officers of the IRB.

3. Responsibility

It is the responsibility of the Medical Director to formally appoint new members and officers after due consultation with the current members of the CHH IRB.

4. Flow chart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Define the composition of the IRB membership	Chairman Member-Secretary IRB members	To be done 60 days before the expiry of a member's appointment
Step 2: Appointment of the Alternate Members	Chairman Member-Secretary IRB members	
Step 3: Opening of the nomination of the new IRB members	IRB members, Hospital management, Department chairs, Section heads	
Step 4: Recommend and submit the list of potential members to the medical director	Chairman	
Step 5: Obtain approval of the appointment of the members and officers	Medical Director	
Step 6: Ensure completion of the membership documents	New member IRB Secretariat	
Step 7: Organize and complete the documents in the membership file	Administrative staff	

5. PROCEDURES

Step 1: Membership composition- The CHH IRB shall be composed of at least seven (9) members.

- Its membership shall be multidisciplinary. The members/alternate members should have a diverse background and experience in order to foster a more comprehensive and efficient review of the 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 Chong Hua Hospital.
- Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the CHH IRB should include a person who will represent the interest and concerns of the community.
- The CHH IRB shall aim for adequate representation of men and women members in order to promote gender sensitivity in its review procedures.
- The CHH IRB shall have representatives from both the older and younger generations.
- IRB Members who are affiliated with Chong Hua Hospital should uphold the protection of human participants over the protection of the Institution from liabilities.
- During review meetings, the CHH 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. 4.2 on Conduct of a Meeting)
- The CHH IRB Chair discusses the qualifications of additional/new members/alternate members with the existing members of the CHH IRB.

Step 2- Appointment of Alternate Members

- Alternate members are members who may substitute for a primary IRB member or a category of member (e.g., physician, nurse or non-medical member). Each alternate IRB member has experience, expertise, background, professional competence and knowledge comparable to that of the primary IRB member(s) whom the alternate would replace.
- Assignment of alternates: An alternate member may be assigned as a substitute for one or more named primary members or for a category of members. Alternates must have qualifications similar to those of the members(s) for whom they are allowed to be a substitute, in compliance with the composition of membership in the CHH IRB.
- Alternate members vote on protocols or other matters at convened meetings only when one of the primary members for whom they are an alternate is not participating in the vote due to absence or conflict of interest. They should only participate when they have, prior to the meeting, adequately reviewed the materials distributed with regard to the protocol or other matters on which they would be voting. The IRB minutes should document the alternate member's votes.
- A designated alternate IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Substitution during a meeting commonly occurs when the primary member is absent from the meeting. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member.

Step 3- Open the nomination of new IRB members/alternate members

- Announce the open nomination process for new IRB members to the CHH-IRB, to hospital management, to department chairs, and section heads.
- Any hospital staff may submit the name of their nominees to the CHH IRB Chair for deliberation, with their corresponding Curriculum Vitae.
- 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 IRB.

- 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 CHH IRB meeting the Chair presents the credentials of the person being nominated. IRB Members discuss and decide by consensus on the final list of nominees to be submitted to the Medical Director. Conflict of interest issues of nominees shall also be discussed.

Step 4- Recommendation to Medical Director: The CHH IRB submits the list of potential members/ alternate members to the Medical Director. This is the final list of nominees to the CHH IRB which is submitted to the Medical Director for final approval.

Step 5- Obtain approval of appointment of CHH IRB members

- The Medical Director reviews the list of nominees and decides on the appointment to be made by issuing a letter of appointment.
- The appointment letter should include conditions of appointment, term of office, and honorarium.
- Members are appointed for a period of three (3) years and renewable for several consecutive terms depending on their performance.

Step 6- Ensuring Continuity of Functions

- To ensure continuity of functions, beginning 2024, the Chairman, Vice Chairman and Member Secretary shall serve for three (3) years. Three (3) new members will serve for two (2) years, while existing CHH IRB members will serve for one year. Thereafter new members appointed annually shall serve for three (3) years.
- Willingness to make public his/her full name, profession, and affiliation as an IRB member
- Members shall disclose all financial accountability related to their work in CHH IRB that may form part of the official record and may be publicly disclose upon request
- Members shall sign the Confidentiality and Conflict of Interest Agreements. The agreement should cover all applications, meeting deliberations, information on research participants and related matters.
- The appointment letter should have an attachment on the responsibilities of an IRB member to:

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

Step 7- Appointment of Non-Medical/Non-Scientific Member- Appointment of Non-Medical/Non-Scientific Member of the CHH IRB should contain an attachment of their responsibilities to:

- Focus on the human subject/participant concerns and protection
- Review the informed consent process and the informed consent forms to ensure adequate and proper application of international and national principles and guidelines.
- The CHH IRB shall adopt some mechanism 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

Step 8- 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 members, they shall sign and date the Term of Reference 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 2023-1.1 HRP-IRB-004) to newly appointed members of the CHH IRB,

one copy for the member and the other for the Membership File. For each protocol that they review, they must disclose the 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 using the standard form (Form 2023-1.1 HRP-IRB-037), and the completed Training Record Form (Form 2023-1.1 HRP-IRB-007) including photocopies of relevant training certificates.

Step 9- Organize and complete the documents in the Membership Files- The CHH IRB creates one membership file for each member, with the following documents in each member's file:

- Letter of Appointment
- Updated Curriculum Vitae
- Training Records and copy of Training Certificates
- Confidentiality and Disclosure of Conflict of Interest Agreement

Step 10-Resignation, Disqualification, and Replacement of Members

- Members may resign their positions by submitting a letter of resignation to the CHH IRB Chair and endorsed to the Medical Director of Chong Hua Hospital.
- A period of transition and proper endorsements can ensue if the letter of resignation is given not less than 2 months from date of resignation or end of term.
- Members must wait for approval of resignation from the Chairman of the IRB, who will communicate such to the Medical Director.
- Members may be separated from the committee by disqualification for valid reasons as determined by majority vote of the committee members.
- 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.

6. History of SOP

Version No.	Date	Authors	Main Change
1	10 September 2010	Dr. Manuel Emerson S. Donaldo	First draft
2	01 January 2014	Atty. Dean G. Decal	Change in the logo from CHH to CHH IRB logo Revised SOP and Form numbering
3	01 September 2014	Atty. Dean G. Decal	Change of IRB SOP in accordance to PHREB SOP Format
4	01 October 2014	Atty. Dean G. Decal	Revised IRB SOP in accordance to PHREB SOP Format
5	01 January 2017	Atty. Dean G. Decal	Revised CHH IRB SOP from Version 04 to Version 05
6	02 October 2017	Atty. Dean G. Decal	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template
7	04 January 2021	Atty. Dean G. Decal	No change
8	04 January 2024	Atty. Dean G. Decal	Revised CHH IRB SOP in accordance with REC re-accreditation and Survey on 30 June 2023
9	21 August 2024	Atty. Dean G. Decal	No Change

7. **References**

- 2017 Department of Health – SOP Version No. 2
- 2020 PHREB SOP Workbook