

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC REEB)</b>	<b>CGHMC REEB SOP Version No. 6</b> Date of Approval: <b>01 December 2019</b> Effective Date: <b>01 Jan 2020</b>
	<b>Chapter 4 Meeting Procedures</b>	

- 4.1 Preparation and Distribution of Meeting Agenda
- 4.2 Preparation of Meeting Minutes
- 4.3 Conduct of a Regular Full Board Meeting
- 4.4 Conduct of Special Meeting

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP Version No. 6 Date of Approval: 01 December 2019 Effective Date: 01 Jan 2020</b>
	<b>Chapter 4 Meeting Procedures</b>	

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 26, 2018	RERB Members	Sections preparation and distribution of meeting agenda and preparation meeting minutes transferred from Chapter 5 to this chapter 4
6	Sep 26, 2018	RERB Members	Added 2 new sections Conduct of full board meeting Conduct of special/emergency meeting

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP</b> <b>Version No. 6</b> Date of Approval: <b>01 December 2019</b> Effective Date: <b>01 Jan 2020</b>
	<b>Chapter 4</b> <b>Meeting Procedures</b>	

#### 4.1. Preparation and Distribution of Meeting Agenda

##### 4.1.1. Purpose

To describe procedures for the preparation and distribution of the RERB meeting agenda

##### 4.1.2. Scope

This SOP provides instructions related to the preparation of the RERB meeting agenda and distribution to inform RERB members and other interested individuals about the items for discussion during a full board meeting.

##### 4.1.3. Responsibility

It is the responsibility of RERB Secretariat, under the supervision of the Secretary-Member, to compile all documents/ information submitted to the RERB within a given period to include them in the next full board meeting agenda for discussion or information of the RERB members.

##### 4.1.4. Process Flow/Steps



	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP Version No. 6</b>
	<b>Chapter 4 Meeting Procedures</b>	<b>Date of Approval: 01 December 2019</b> <b>Effective Date: 01 Jan 2020</b>

#### 4.1.5. Detailed Instructions

4.1.5.1. Collect all documents submitted to the RERB within a given period and put them in the full board meeting agenda for discussion or information of the RERB members.

4.1.5.2. The standard notice of meeting or agenda contains the ff: (Form 29)

- Date of preparation
- Date, time and venue of meeting
- Agenda items
- New protocols for initial review of full board
- Resubmission
- Amendments
- Progress reports
- Continuing Review
- Final reports
- SAE reports
- Protocol violation/deviation
- Site Visit Reports
- Expedited Meeting Reports
- Other matters

4.1.5.3. Recommendations on protocols requiring clarifications from the principal Investigator during an RERB full board meeting are made by CGHMC RERB primary reviewers, who request the Secretariat to inform the investigators about the meeting schedule. The time slot for their appearance at the RERB meeting is communicated to them.

4.1.5.4. The Secretariat informs and consults the Chair about the agenda items. Soft copies of the agenda of meeting and minutes of previous meeting are sent to all RERB members through email at least a week before the scheduled meeting.

4.1.5.5. The Secretariat arranges the venue and other logistics for the meeting at least one week before the scheduled meeting prior to preparation of the notice of meeting.

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMCRERB)</b>	<b>CGHMC RERBSOP Version No. 6</b>
	<b>Chapter 4 Meeting Procedures</b>	<b>Date of Approval: 01 December 2019 Effective Date: 01 Jan 2020</b>

4.1.5.6. The Secretariat makes copies of the notice of meeting containing the approved agenda to the CGHMCRERB members, at least one week before the meeting.

4.1.5.7. The Secretariat communicates with the RERB members to confirm their attendance and ensure quorum will be reached for the next board meeting.

4.1.5.8. The Secretariat files a copy of the agenda in the Agenda and Minutes folder.

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP Version No. 6</b> Date of Approval: <b>01 December 2019</b> Effective Date: <b>01 Jan 2020</b>
	<b>Chapter 4 Meeting Procedures</b>	

## 4.2. Preparation of Meeting Minutes

### 4.2.1. Purpose

To describe procedures for the preparation and approval of the minutes of the RERB full board meeting

### 4.2.2. Scope

This SOP provides instructions related to the preparation of the RERB full board meeting minutes and its approval by the RERB members.

### 4.2.3. Responsibility

It is the responsibility of RERB Secretariat, under the supervision of the Member-Secretary, to document the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the RERB meeting agenda.

### 4.2.4. Process Flow/Steps



	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC REIRB)</b>	<b>CGHMC REIRB SOP Version No. 6</b> Date of Approval: <b>01 December 2019</b> Effective Date: <b>01 Jan 2020</b>
	<b>Chapter 4 Meeting Procedures</b>	

#### 4.2.5. Detailed Instructions

- 4.2.5.1. The Secretariat uses Form 30 as a template to organize the meeting discussion in preparation to writing the minutes ahead of the meeting date.
- 4.2.5.2. The Secretariat documents the proceedings of the meeting as the meeting progresses by writing directly into the template prepared.
- 4.2.5.3. The Secretariat reviews the proceedings prepared during the meeting and verifies that it contains the following sections:
- Date and venue of meeting
  - Member attendance (members present and absent) to determine quorum
  - Guests and observer attendance
  - Time when the meeting was called to order
  - Presiding officer
  - Conflict of interest declaration by REIRB members
  - Discussion of items based on the Meeting Agenda
  - Decisions and recommendations arrived at during the meeting
  - Name and signature of person who prepared the Minutes
  - Name and signature of the Chair with the date of approval
- 4.2.5.4. Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.
- 4.2.5.5. The Secretariat submits a complete draft of the minutes to the member-secretary within one week after the meeting for corrections, and submits the corrected draft to the Chair for approval.
- 4.2.5.6. The Secretariat uses the information in the minutes to communicate full board REIRB decisions to respective Principal Investigators.

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP Version No. 6</b>
	<b>Chapter 4 Meeting Procedures</b>	<b>Date of Approval: 01 December 2019 Effective Date: 01 Jan 2020</b>

4.2.5.7. The minutes of the RERB full board meeting, once they are finalized, are sent to the members for comments or correction. The minutes are formally approved during the next full board meeting.

4.2.5.8. The Secretariat files the signed minutes in the Minutes of the Meeting folder of the RERB.

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP Version No. 6</b> Date of Approval: <b>01 December 2019</b> Effective Date: <b>01 Jan 2020</b>
	<b>Chapter 4 Meeting Procedures</b>	

#### 4.3 Conduct of a Full Board Meeting (Regular)

##### 4.3.1. PURPOSE

To describe the procedures in the conduct of a regular full board RERB meeting

##### 4.3.2. SCOPE

From start of the meeting to adjournment

##### 4.3.3. RESPONSIBILITY

It is the responsibility of the RERB Chair to preside over the meeting and exercise leadership to enable the RERB members and staff to fulfill their roles in the review of protocol and protocol-related documents submitted to the RERB.

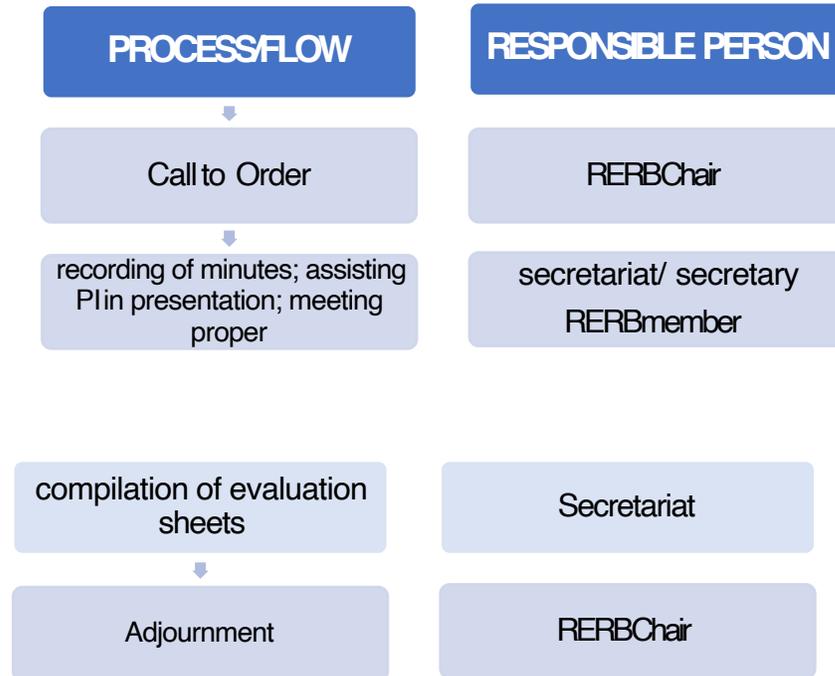
It is the responsibility of the Member-Secretary to ensure that quorum will be met and to take down the minutes in real-time.

It is the responsibility of the RERB members to prepare and participate in the board meeting to ensure good review and take appropriate action in relation to submitted protocol documents.

It is the responsibility of the secretariat staff to prepare and make available all documents needed during the meeting, record the meeting and assist the principal investigators for their oral presentation.

##### 4.3.4. FLOWCHART

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP</b> <b>Version No. 6</b> Date of Approval: <b>01 December 2019</b> Effective Date: <b>01 Jan 2020</b>
	<b>Chapter 4</b> <b>Meeting Procedures</b>	



#### 4.3.5. Detailed Instructions

##### 4.3.5.1. Start of meeting

4.3.5.1.1. The RERB meetings shall be conducted in accordance with the sequence as prepared in the Agenda.

- The Chair shall call the meeting to order
- The Chair shall ask the Secretary if there is a quorum.
- Quorum will be declared if there's 50%+1 present. Moreover, at least 1 member whose primary area of interest is 1 non-medical and at least 1 member who is independent of the institution (who can be represented by the non-medical as the case may be) must be present.
- If there is a quorum, the Chair shall proceed. If no quorum exists, the Chair shall declare adjournment.
- The Chair shall ask for the approval of the agenda.

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP Version No. 6</b> Date of Approval: <b>01 December 2019</b> Effective Date: <b>01 Jan 2020</b>
	<b>Chapter 4 Meeting Procedures</b>	

- The Chair shall ask if any member of the RERB has a conflict of interest in any of the proposals for review. Conflict of Interest is present when an RERB member has affiliation with a Principal Investigator or institute which will undermine his/her ability to make a free and independent evaluation. If any member of the RERB declares a conflict of interest in any of the protocols for review, the Chair shall request the concerned member not to participate in the decision-making of the specified protocol. If there is no declaration of any conflict of interest, the Chair shall proceed with the next item in the Agenda.

#### 4.3.5.2. Conduct of meeting

- 4.3.5.2.1. The IERC Chair shall present the Minutes of the Previous Meeting for Reading and Approval discuss matters arising from the minutes
- 4.3.5.2.2. Presentation of Clinical Trial Protocols/Research Proposals
- 4.3.5.2.3. The RERB Chair shall call and introduce the presenter
- 4.2.5.2.4. The RERB Chair shall facilitate interpolation
- 4.2.5.2.5. The RERB Chair shall present other items as listed in the Agenda Items for review and discussion:
  - Protocols for modification
  - Protocol Amendments
  - Serious Adverse Events Reports
  - Protocol Deviations/ non-compliance
  - Clarificatory Interview
  - Other administrative matters
  - Items for information
  - Other Matters

#### 4.3.5.3. Adjournment

- 4.3.5.3.1. The Chair shall adjourn the meeting after confirmation of the date of the next Regular Meeting.
- 4.3.5.3.2. The Secretariat shall turn off the recorder and distribute relevant documents to members.

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMCRERB)</b>	<b>CGHMC RERBSOP Version No. 6</b>
	<b>Chapter 4 Meeting Procedures</b>	<b>Date of Approval: 01 December 2019</b> <b>Effective Date: 01 Jan 2020</b>

The secretariat shall call Housekeeping Unit to clean the meeting venue.

The secretariat shall collect all binders and keep these on file at the RERB Office

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP Version No. 6</b> Date of Approval: <b>01 December 2019</b> Effective Date: <b>01 Jan 2020</b>
	<b>Chapter 4 Meeting Procedures</b>	

#### 4.4. Conduct of Special/ Emergency Meeting

##### 4.4.1. PURPOSE

To describe the procedures in recognizing and evaluating events/situations that will require an emergency/special meeting and the conduct of such meetings.

##### 4.4.2. SCOPE

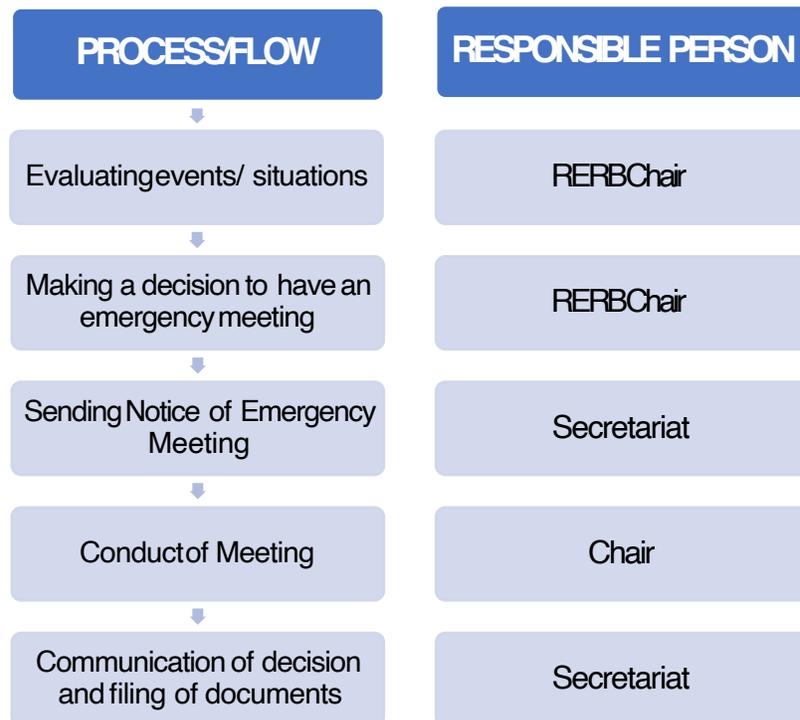
From evaluating events or situations making a decision, giving notice, and conducting emergency meetings, to adjournment and communication of decisions made.

##### 4.4.3. RESPONSIBILITY

It is the responsibility of the RERB Chair to call for an emergency/special meeting as appropriate

It is the responsibility of the secretariat to contact and inform RERB members, including resource persons about the meeting

##### 4.4.4. FLOWCHART



	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP Version No. 6</b> Date of Approval: <b>01 December 2019</b> Effective Date: <b>01 Jan 2020</b>
	<b>Chapter 4 Meeting Procedures</b>	

#### 4.4.5. Detailed Instructions

4.4.5.1. Evaluating events/situations and deciding to call for an emergency meeting of the RERB:

4.4.5.1.1. The following events/situations will require an emergency meeting of the RERB:

- Occurrence of an unexpected serious adverse event that will be life-threatening to study participants
- Recall of study drug by regulatory authorities
- Matter of life and death
- Other urgent issues as identified by RERB members or administration officials

4.4.5.2. After an evaluation of the event/situation, the RERB Chair shall call for an emergency meeting of the RERB

4.4.5.3. The Secretariat shall send a Notice of Emergency Meeting to RERB members, including resource persons, if needed.

4.4.5.4. The Secretariat shall prepare the Agenda and relevant materials for the emergency meeting

#### 4.4.5.5. Conduct of Meeting

4.4.5.5.1. The RERB Chair shall determine the presence of a quorum.

4.4.5.5.2. The RERB Chair shall immediately present the relevant issues for discussion and shall ensure that the issues are resolved in the meeting.

4.4.5.5.3. The RERB shall make a decision on the issues by majority vote. The Secretary shall record and take minutes of the meeting.

#### 4.4.5.6. Communication of decision and filing of documents

4.4.5.6.1. The Secretariat shall prepare the Notice of Action to be signed by the RERB Chair

4.4.5.6.2. The Secretariat shall deliver the notification to the person concerned.

4.4.5.6.3. The Secretariat shall file the relevant materials and documents appropriately