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1. Purpose

Since CHONG HUA HOSPITAL IRB considers protection of the rights and welfare of the human subjects participating in a clinical investigation/research approved by the CHH IRB as its primary responsibility, Informed Consent documents reviewed by the CHH IRB may routinely contain the statement, "Questions regarding the rights of a participant/patient may be addressed to the CHH IRB Chairperson with CHH, *address and/or phone number."* On some occasions, the first contact a participant/patient may have would be the CHH IRB Secretariat.

This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as participants in any approved research study.

2. Scope

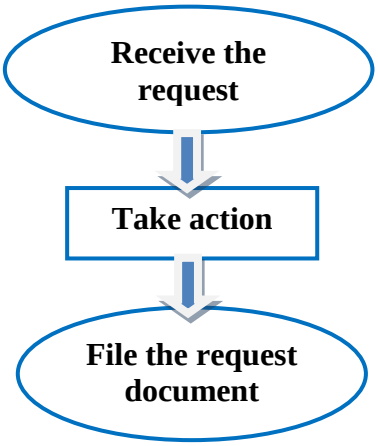
This SOP applies to all requests concerning the rights and well-being of the research participants participating in studies approved by the CHH IRB.

3. Responsibility

The Institute's policy designates the Chairperson of the CHH IRB as the person responsible for communicating with participants/patients regarding their rights as study participants. Delegation of this responsibility to another CHH IRB member is acceptable as long as the delegation is documented (in writing). Delegation to non-IEC members is not permitted.

It is the responsibility of all Staff and CHH IRB members acting on behalf of the CHH IRB to facilitate participant/patient requests within the scope of their responsibilities.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I		CHH IRB Staff Secretary/Secretariat
II		CHH IRB Members and Chairperson
III		CHH IRB Staff Secretary/Secretariat

5. Detailed Instructions

5.1 Receive the request

- The CHH IRB staff secretary receives the inquiry or requests from research participants/patients.
- Record the request and information in the request record form (Form HRP IRB-022, see ANNEX 1)
- Communicate with the CHH IRB about study participant rights for instruction.
- Refer the inquiry to the CHH IRB Chairperson to be done in writing.
- CHH staff secretary may provide assistance in contacting the Chairperson, but will not provide comments/opinions about the inquiry.
- The Chairperson shall document the communication for the CHH IRB study file, request follow-up information, provide advice as required, inform the other CHH IRB members about the inquiry, follow-up at the next CHH IRB meeting, or delegate these tasks to the CHH IRB Secretariat or members.

5.2 Take Action

- Investigate the fact.
- Record information and any action or follow-up taken in the form (Form HRP IRB-022, see ANNEX 1)
- Sign and date the form.
- Report to the CHH IRB about the action/s taken and the outcome.

5.3 File the request document

– Secretary to keep the record form in the "response" file.
– Secretary to keep a copy in the study file.
– Store the file in the appropriately labeled shelf.

6. ANNEX

ANNEX 1

CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

REQUEST RECORD FORM

HRP-IRB-022

Requestor's/Research Participant's Name:			Starting date of participation :
Request from :	❑ Telephone No. ❑ Fax No	❑ Mailed letter / Date ❑ E-mail / Date	❑ Walk-in / Date / Time ❑ Others, specify
Contact Address:			Phone:
Protocol Number and Title of the Study:			
What are requested?			
Action/s taken:		Outcome:	
Received by : (NAME AND SIGNATURE)			Date Received:

REQUEST RECORD FORM

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7. References

- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- National Ethical Guidelines for Health Research 2011 PNHRS