Title: Response to Research Participants' Requests

SOP Code: SOP/17/V1.1

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1. Purpose

Since the NIRRH Ethics Committee for Clinical Studies considers protection of the rights and welfare of the human subjects participating in a clinical investigation/research approved by the IEC as its primary responsibility, Informed Consent documents reviewed by the IEC may routinely contain the statement, "Questions regarding the rights of a participant/patient may be addressed to the Member Secretary with the NIRRH Ethics Committee for Clinical Studies *address and/or phone number*. On some occasions, the first contact with the participant/patient would be the IEC Secretariat.

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

2. Scope

This SOP applies to all responses to requests from participant concerning their rights and well-being while participating in studies approved by the IEC.

3. Responsibility

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

4. Flow chart

No.	Activity	Responsibility
1	Receive the request ↓	IEC Members and Secretariat
2	Take action ↓	IEC Members and Chairperson
3	File the request document	IEC Secretariat

5. Detailed instructions

5.1 Receive the request.

- The IEC member receives the inquiry or requests from research participants/patients.
- Record the request and information in the request record form (Form AF/EC/01/17/V1.1 see ANNEX 1)
- Communicate with the IEC about study participant rights for instruction (if required).
- Refer the inquiry to the IEC Chairperson in writing (if required).
- Staff of the institute may provide assistance in contacting the Member Secretary, but will not provide comments/opinions about the inquiry.

5.2 Take Action

- Investigate the fact.
- Record information and any action or follow-up taken in the form AF/01/17/V1.1.
- Take signature of the Chairperson and the Member Secretary and date the form.
- Report to the IEC about the action taken and the outcomes.
- Communicate the reply with the participant and keep the record.

5.3 File the request document

- Keep the record form in the "response" file.
- Keep a copy in the study file.
- Store the file in the appropriately labeled shelf.

6. References

6.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

6.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

6.3 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

7. ANNEX

ANNEX 1 AF/EC/01/17/V1.1 Request Record Form

ANNEX 1 **AF/EC/01/17/V1.1**

Request Record Form

Date Received:	
Received by :	
Request by :	□ Telephone call No……..……... □ Fax No…….… □ Mailed letter / Date…… …….……. □ E-mail / Date…….…… □ Walk-in / Date / Time…….…….. □ Other, specify ……..…….
Participant's Name:	
Contact Address:	
Phone:	
Title of the Participating Study	
Starting date of participation :	
What is the request?	
Action taken:	
Outcome:	

Signature of Member Secretary **Signature of the Chairperson**