



NKTIREC FORM 8.0: REQUESTS, QUERIES, AND COMPLAINTS

INSTRUCTIONS:

This form should be accomplished by any party communicating requests, queries, and complaints or grievances for information or action by the NKTIREC. In case of communication from research subjects or participants, the NKTIREC personnel can encode the information on their behalf if needed. Information reported in this form is processed either as a study-protocol-related or non-study-protocol-related communication, as the case may be. For protocol-related communication, put the relevant study protocol information below; if not, put N/A. If necessary, a letter may be attached to this form by the sending party, but a summary of the nature of communication should still be encoded in this form to allow proper filing of communication. This form should be printed in A4 size paper and duly signed by the personnel accomplishing this form.

NATURE OF COMMUNICATION		
<input type="checkbox"/> Study-protocol-related		
<input type="checkbox"/> Non-study-protocol-related		
NKTIREC CODE:		
STUDY PROTOCOL TITLE:		
APPROVAL DATE: <dd/mm/yyyy>		
PRINCIPAL INVESTIGATOR:		
Email:	Telephone:	Mobile:
STUDY SITE: <Name and address>		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	Telephone:	Mobile:
DATE RECEIVED: <dd/mm/yyyy>		
1. RECEIVED BY (NKTIREC Personnel): <TITLE, NAME, SURNAME>		
2. COMMUNICATION DELIVERED/SENT THROUGH:		
2.1 <input type="checkbox"/> Telephone		
2.2 <input type="checkbox"/> Fax No		
2.3 <input type="checkbox"/> Regular Mail dated: <dd/mm/yyyy>		
2.4 <input type="checkbox"/> E-mail dated: <dd/mm/yyyy>		
2.5 <input type="checkbox"/> Walk-in (indicate date/time)		
2.6 <input type="checkbox"/> Other, specify:		
3. PERSON SENDING THE COMMUNICATION		
3.1. <TITLE, NAME, SURNAME>		
3.2. Address: <Street Number, Street, Barangay, City, Postal Code>		
3.3. Telephone: <area code, number>		



3.4. Mobile: <Provider code, number> 3.5. Email:
4. CONNECTION/RELATION OF PERSON TO THE STUDY PROTOCOL 4.1. <input type="checkbox"/> Study participant 4.2. <input type="checkbox"/> Other: <specify> 4.3. <input type="checkbox"/> Not applicable
5. TYPE OF CONCERN
5.1. <input type="checkbox"/> Requests <specify>
5.2. <input type="checkbox"/> Queries <specify>
5.3. <input type="checkbox"/> Complaint <specify>
5.4. <input type="checkbox"/> Others <specify>
6. Signature of Person Accomplishing this form:

RECOMMENDATIONS (for NKTi REC use only)

REFERRED TO		
<input type="checkbox"/> Full Board Review <input type="checkbox"/> Expedited Review <input type="checkbox"/> Other: <Specify>		
RECOMMENDED ACTION:		
<input type="checkbox"/> NO FURTHER ACTION <input type="checkbox"/> REQUEST INFORMATION: <specify> <input type="checkbox"/> RECOMMEND FURTHER ACTION: <specify> <input type="checkbox"/> PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE		
NKTi REC SECRETARIAT	Signature	_____
DATE: <dd/mm/yyyy>	Name	<Title, Name, Surname>

If study-protocol-related, this form should be reviewed and signed by primary reviewer

PRIMARY REVIEWER	Signature	_____
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>