MAHIDOL UNIVERSITY
Wisdom of the Land

Writing EC Submission

DEPARTMENT OF TROPICAL HYGIENE, FACULTY OF TROPICAL MEDICINE

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https://sqonline.ucsd.edu/2014/03/frankensteins-monster-an-experiment-in-physiology-and-ethics/

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Do I need Ethics Approval?

Observational or Experimental study in Human

Human Specimens

Human data
- Public health data
- Medical records
- Questionnaire

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Do I need TropMed EC approval?

- Trop Med Staff
  - PI study in or out of faculty
  - Co-Investigator study in the faculty

- Trop Med Staff
  - Co-I study out of faculty
- Non-TM Staff
  - Study in the faculty (No TM collaborator)

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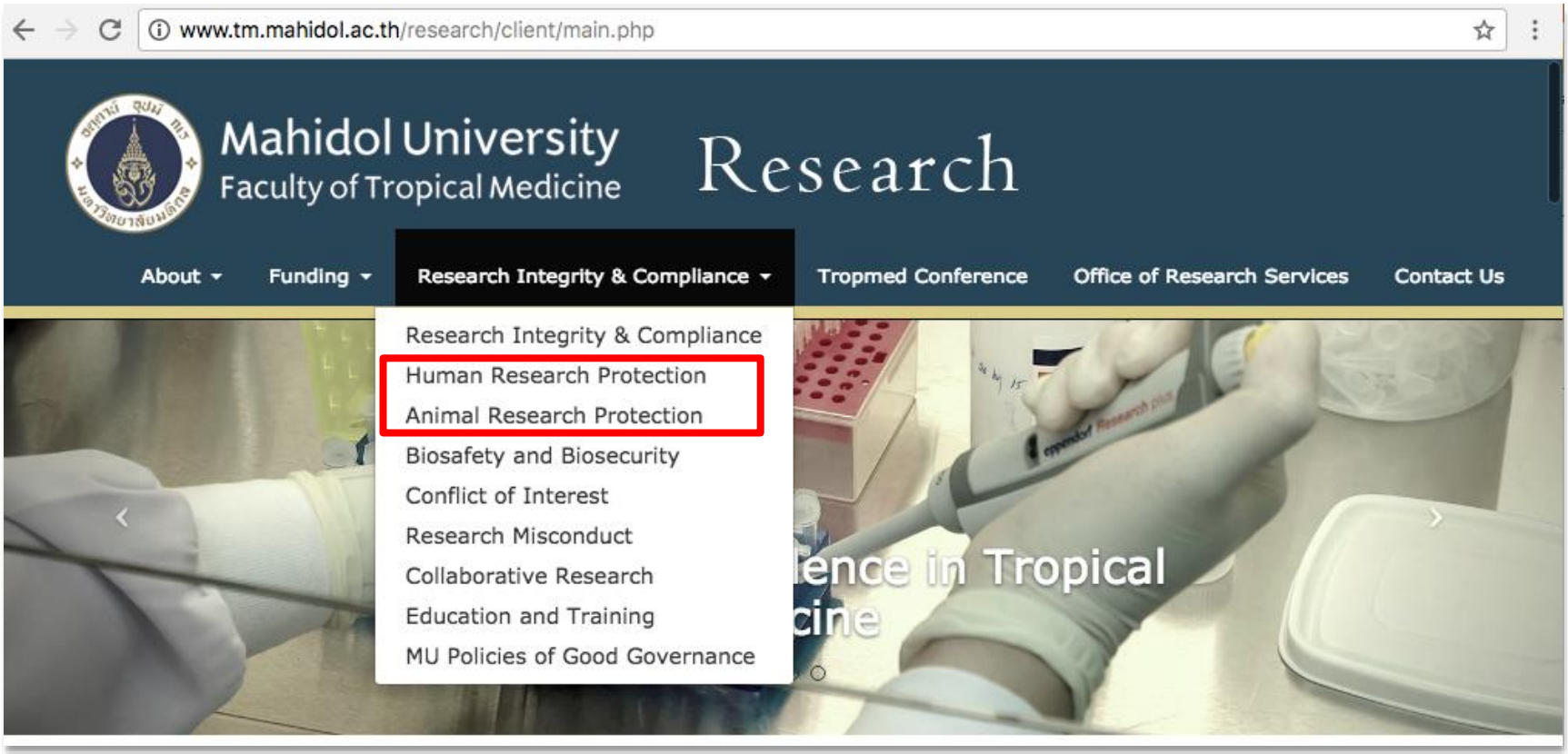
Get Started



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Mahidol University
Faculty of Tropical Medicine

Research

About ▾ | Funding ▾ | Research Integrity & Compliance ▾ | Tropmed Conference | Office of Research Services | Contact Us

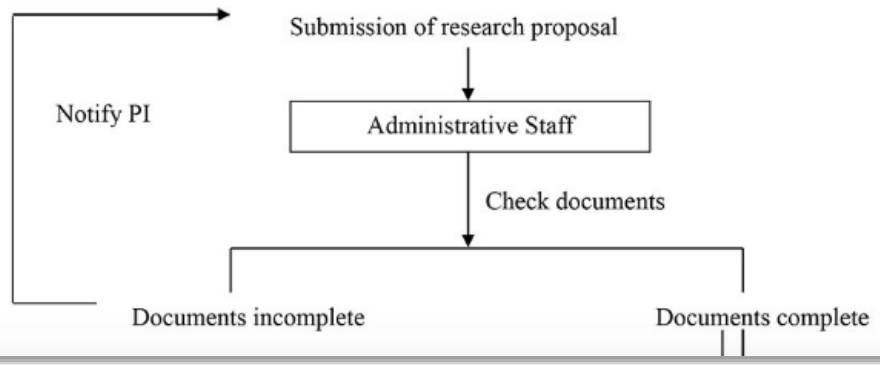
- Human Research Protection
- Human Ethics
- EC Committee
- EC Review Process
- Submission Guidelines
- SOP / Submission Forms
- Accreditation/Recognitions
- Activities
- Training +
- MU Multicenter Research +
- References / Links
- EC Meeting Schedule

Do I need Ethics Approval?

If your project involves human subjects, you require ethics committee approval. This is to ensure the safety of the subjects, protection of confidential information, and appropriate ethical treatment of those involved in your research. There are two panels, one for clinical studies, and one for non-clinical (biomedical and observational) studies, and there are three routes to EC approval, full board review, expedited review, and exemption from review. To learn more about each route, please click the links below.

Process diagram | Full Board Review | Expedited Review | Exemption Review | Post-Review

Process diagram



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Types of Ethical Review

(Decision made by EC chair person)

Exemption

- Minimal risk
- Does not include identifiers
- Topic not sensitive
- Non-vulnerable subjects

Expedited

- Minimal risk
- May include identifiers
- Non- or Mild-sensitive topic
- May include vulnerable population

Full Board

- More than minimal risk
- Involve procedures that require additional safeguards

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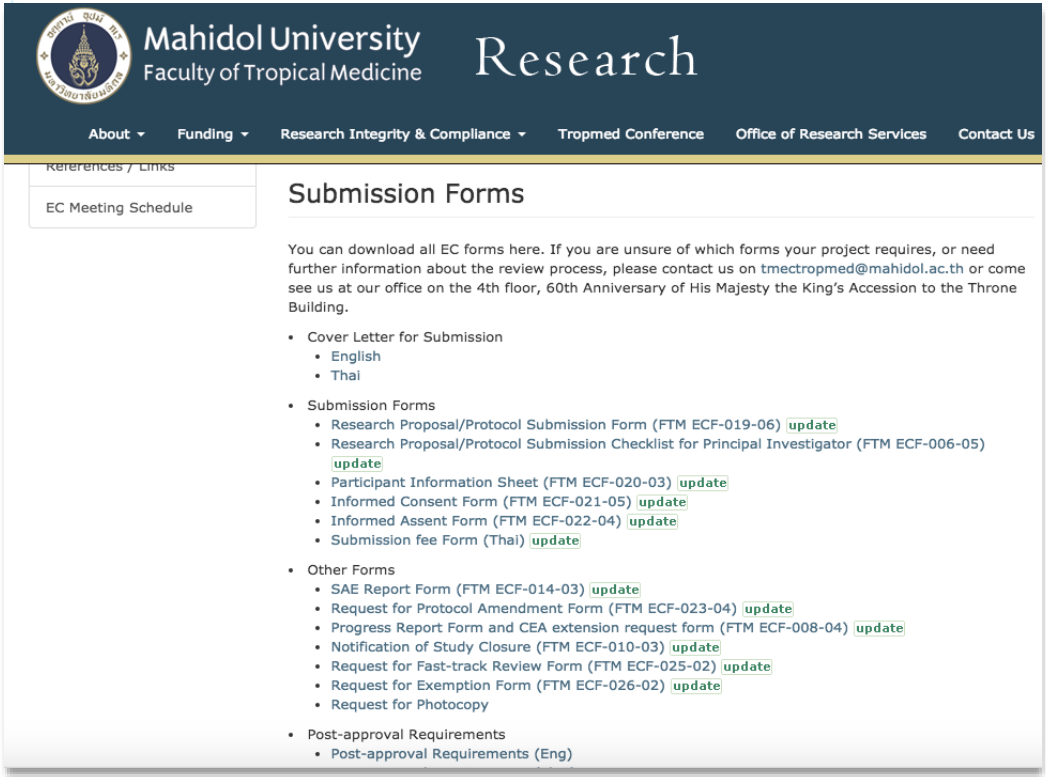
Submission Forms



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References / Links

EC Meeting Schedule

Submission Forms

You can download all EC forms here. If you are unsure of which forms your project requires, or need further information about the review process, please contact us on tmectropmed@mahidol.ac.th or come see us at our office on the 4th floor, 60th Anniversary of His Majesty the King's Accession to the Throne Building.

- Cover Letter for Submission
  - English
  - Thai
- Submission Forms
  - Research Proposal/Protocol Submission Form (FTM ECF-019-06) update
  - Research Proposal/Protocol Submission Checklist for Principal Investigator (FTM ECF-006-05) update
  - Participant Information Sheet (FTM ECF-020-03) update
  - Informed Consent Form (FTM ECF-021-05) update
  - Informed Assent Form (FTM ECF-022-04) update
  - Submission fee Form (Thai) update
- Other Forms
  - SAE Report Form (FTM ECF-014-03) update
  - Request for Protocol Amendment Form (FTM ECF-023-04) update
  - Progress Report Form and CEA extension request form (FTM ECF-008-04) update
  - Notification of Study Closure (FTM ECF-010-03) update
  - Request for Fast-track Review Form (FTM ECF-025-02) update
  - Request for Exemption Form (FTM ECF-026-02) update
  - Request for Photocopy
- Post-approval Requirements
  - Post-approval Requirements (Eng)

1. Cover Letter
2. Research Proposal submission form
3. Research Proposal submission checklist
4. Research Proposal
5. Participant Information Sheet (if applicable)
6. Informed Consent Form (if applicable)
7. Informed Assent Form (if applicable)
8. Submission fee Form
9. Request for Exemption Form (if applicable)

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	Research Proposal Submission Form	
	Document No.: FTM ECF-035-00	Page 1 of 7

RESEARCH PROPOSAL SUBMISSION FORM

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Identify your study

Retrospective Study and/or
No-direct Contact With Human Subjects

- ☐ Study using stored specimens,
- ☐ Study using stored tissues,
- ☐ Study using stored fluids,
- ☐ Study using stored cells
- ☐ Study using stored medical records
- ☐ Others……..……

Study Involving Specimen Collection

- ☐ Clinical trial phase…/ Intervention study
- ☐ Bioequivalence/ pharmacokinetic drug study
- ☐ Prospective epidemiological research
- ☐ Laboratory study

Study Not Involve Specimen Collection

- ☐ Intervention without specimen collection
- ☐ Social/ behavioral research
- ☐ Prospective epidemiological research

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Read the Instruction!

- Use submission form appropriated to your study
- Complete all parts in plain English or Thai, without acronyms
- If a section is not applicable for your research, mark NA
- Limit 50 pages with Times New Roman font size not less than 12
- Keep an electronic copy for revising in the future
- Remove all instructions in italics from the final protocol

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Information needed

- **PART A:** Project Information
- **PART B:** Details of the Study
- **PART C:** Ethical Consideration

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PART A: Project Information

A1. TITLE OF THE STUDY IN THAI AND ENGLISH

(Title of the study, study identifying number and date, if any. This title will be recorded on EC database and used in all correspondence in relation to this study.)

A2. RESEARCH PROPOSAL VERSION DATE: ……

Type of submission
- ☐ Initial review (first time submission)
- ☐ Revision according to TMEC suggestions No. ……..….
- ☐ Amendment No. ……..….

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PART A: Project Information

A3. PRINCIPAL INVESTIGATOR NAME:

- ☐ **Faculty Staff** (Go to A4.1)
- ☐ **Student, ID**……..… (Please check the following, and go to A4.2)
  - ☐ Research for Thesis
  - ☐ M.Sc. (Trop. Med.)
  - ☐ Ph.D. (Trop. Med.)
  - ☐ Ph.D. (Clin. Trop. Med.)
  - ☐ Research for Thematic Paper
  - ☐ M.C.T.M.
  - ☐ M.C.T.M. (T.P.)
  - ☐ Other, specify ……
- ☐ **Other** ……. (Please specify, and go to A4.1)

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PART A: Project Information

A4. LIST NAME, AFFILIATION AND CONTACT DETAILS OF ALL INVESTIGATORS

A4.2 For students

Name	Position	Contact address	E-mail address
	Principal Investigator	Your department	
	Advisor		
	Co-advisor		
	Co-advisor		

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PART A: Project Information

A8. IS THE PROJECTS A SINGLE CENTER OR MULTI-CENTER?

- ☐ Single center
- ☐ Multicenter (within Thailand)
  Please specify the study sites …….....
- ☐ Multicenter (International)
  Please specify the study sites ……..…

Multicenter:
Different investigators in different centers

A9. PROJECT SUMMARY IN THAI AND ENGLISH

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PART A: Project Information

A10. SOURCE(S) OF FUNDING/ SPONSOR(S) AND BUDGET (Information required for review and consideration)

☐ Funded by: **Faculty of Tropical Medicine**…….*(Please also specify funded year)*
Budget amount: ……..……..

☐ Expecting fund from: ……
(State the name of the funding body and status of application)
Budget amount:……..…….……

A11. DECLARE CONFLICT OF INTEREST

(If PI or Co-PI have Conflict of Interest with the Institution/Company funding this project, please describe who has the conflict, with what institution and how.)

PI and Co-PI have no Conflict of Interest.

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PART B: Details of the Study

B4. STUDY TIMELINES:

Describe:

The duration of an individual participant's participation in the study.

The duration anticipated to enroll all study participants.

The estimated duration for the investigators to complete this study (complete primary analyses).

Timeline should be feasible and flexible:

"One year after EC approval"

Avoid writing exact date/month if you are not certain that the research will be able to conduct on that period.

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PART B: Details of the Study

B5.3 Sample size calculation

- Consider based on primary objectives
- Provide references or rationale of choosing each parameter in sample size calculation

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B5.5 Sample size calculation

Sample Size Estimation: The sample size will be calculated using the following formula:

$$n = \frac{z^2_{\alpha/2}\, p(1-p)}{d^2}$$

In 2008, the prevalence of Anxiety and depression in adult at Jigme Dorji Wangchuk National Reffereal Hospital (JDWNRRH) Thimphu, Bhutan, was reported at 29.3% with depression and 19.2% with anxiety disorder (3). The study conducted for the prevalence in Mullana, Ambala, India had shown 29.9% adolescents have evidence of depression (8).

Prevalence among adolescent is unknown in Bhutan because no former study has done in country for anxiety and depression in adolescent, therefore, in this study the estimated anxiety and depression prevalence in Bhutan adolescent is assumed at 30% or p=0.3

d = acceptable error in estimating prevalence = 0.05

α = probability of type I error = 0.05 (2-sided),

$z_{0.025} = 1.96$

$$n = \frac{z^2_{\alpha/2}\, p(1-p)}{d^2} = \frac{(1.96)^2(0.3)(0.7)}{(0.05)^2} = 323$$

The sample size in this study is added 10% dropout to 323 to the actual study population. Thus in this study, approximately 350 participants will be selected from six selected

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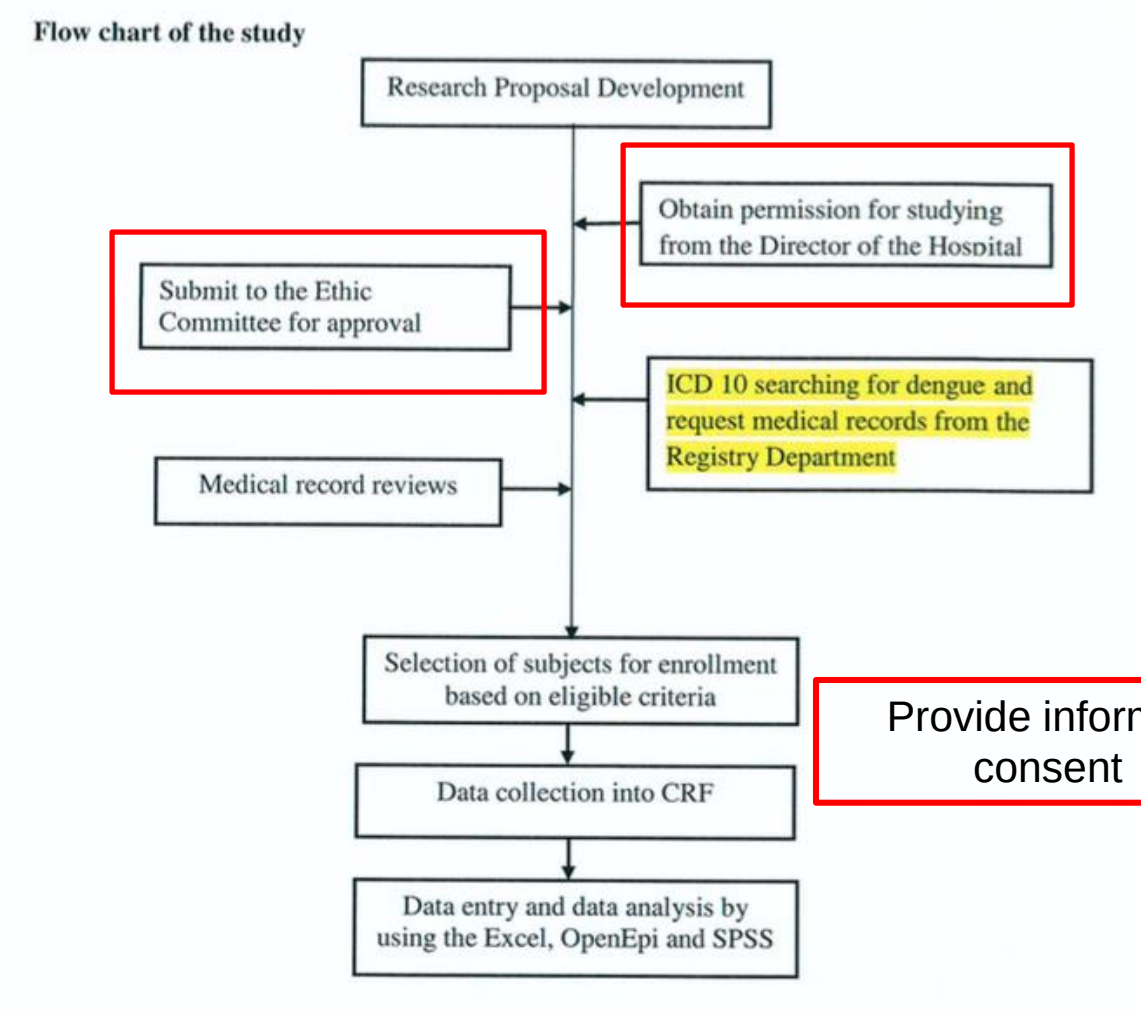
B6.3 Schematic diagram of study design, procedures and stages, step-by-step



Provide informed consent

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Data Confidentiality

Participants' privacy and confidentiality will be strictly protected. Personal information collected in the research work will be kept as numerical codes which will be recorded and stored. The results of this study will be presented in the overview of subjects that do not identify an individual.

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Data Confidentiality

The participant's information will be kept confidentially. It will not be subject to an individual disclosure, but will be included in the research report as a part of the overall results. The individual information may be examined by group of personnel.eg. Ethics committee, and from funding organization. The participant has the right to withdraw from the project at any time without prior notice. The information collected from the participants will be kept only 2-3 months till the final printing of the Thematic paper, After that together with the Advisors and Principal Investigator, the document collected from participants will be cancelled.

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PART C: Ethical Consideration

C2. BALANCE OF RISK AND BENEFIT

C2.1-2.2 Risk and Preventive Measures

Risks	Preventive Measures for Risks
• Feel discomfort (interview, questionnaire)	• The participants can stop or withdrawn from the study at anytime.
• Pain or bruise or infection at blood withdrawal site (blood drawn)	• Procedures performed by trained nurses using standard sterile techniques. The participant will be observed for 15 minutes after blood drawn.
• Adverse effect from the intervention	• Observation period after intervention. • - Can withdraw from the study at anytime.

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Benefits of the Study

- Indirect benefit
  - New knowledge/techniques that can help…….
- Direct benefit (to participants)
  - Usually limited
  - Receive health education, check-up

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Vulnerable Research Participants

- Not able to make informed decisions for themselves
- Can easily be manipulated

Check whether your study involves any of the following vulnerable research

- ☐ Prisoners
- ☐ Pregnant women
- ☐ Mentally ill persons
- ☐ Cancer or terminally ill patients
- ☐ Neonates/infants/children (aged <18)
- ☐ HIV/AIDS patients
- ☐ Institutionalized persons e.g. military, students, etc.
- ☐ Others (please specify).....

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Informed Consent Process

- Method of invitation the participants (Who, When, Where)
- Where the consent process will take place
- Steps taken to minimize coercion
- Steps taken to ensure participants' understanding

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Informed Consent Documents

Age	Informed Consent/ Assent Form	Participant Information Sheet
< 7 years	ICF for parent permission	For parents
7 - <13 years	ICF for parent permission IAF for young child	For parents and young children
13 - <18 years	Same ICF for child and Parent	For parents and children
≥18 years	ICF for adult	For adult

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Compensation

- For travel and time lost
- Appropriate amount (money or gift)
- Provide at each visit
- Provide reason, if no compensation provided

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Responsible and contact persons

- Name (a person)
- Address
- Mobile phone number

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