International Union against TB and Lung Disease
Ethics Advisory Group (EAG)

STANDARD OPERATING PROCEDURE

SOP-EAG 001 vs1 **IMPLEMENTATION DATE:**

SUBJECT:	**Procedure for the Approval of Research on Human Participants by the International Union against TB and Lung Disease Ethics Advisory Group (EAG)**
DIVISION / SCOPE:	**International Union against TB and Lung Disease Ethics Advisory Group (EAG)**
AUTHOR: **REVISION:**	**EAG Secretariat**
PURPOSE:	This procedure describes the process to be followed by the EAG for the approval of Research on Human Participants to ensure all proposals for studies in which the Union or Union staff are involved approved by the EAG are in compliance with the following requirements:
PREVIOUS VERSIONS / ***(REASON FOR REVISION)***	N/A
CONTENTS:	
APPROVALS:	**Signature of Chair of EAG:** **Date:**

1. DEFINITIONS AND ABBREVIATIONS

Clinical Investigation	Means any experiment that involves a test article and one or more human participants. The terms "research", "clinical research", "clinical study", "clinical trial" and "clinical investigation" are considered synonymous for EAG policies and procedures.
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
IRB	Institutional Review Boards (USA term for IEC)
IEC	Independent Ethics Committee (ICH GCP term)
EAG	Ethics Advisory Group

2. REFERENCES

- ICH Harmonized Guideline – Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH – E6(R2) – Current Step 4 version dated 9 November 2016
- Declaration of Helsinki 2013
- Belmont Report https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf.
- The Common Rule: US 45 CFR 46 https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

3. EAG COMPOSITION

The EAG shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the Union or its staff. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. (For full election process please refer to SOP 3)

4. PROCEDURE FOR APPROVAL OF HUMAN RESEARCH TO BE CONDUCTED UNDER THE EAG

The EAG Secretariat will handle the administration of documents that are received for EAG approval according to their procedures. Their procedures require that the following documentation be available for application of EAG approval:

- The official EAG application form
- Protocols / Amendments
- Investigator's Brochures (if required)
- Protocol Summaries
- Participant Information Sheets (if required)
- Participant Informed Consent Forms (if required)
- Summary of Participant Visits and Payment Schedule (if required)
- Commitments and Declaration of Investigators (if required)
- Investigator's Curriculum Vitae
- The local ethics committee approval certificate
- Or authorised approval (where no local ethics committee exists)
- Financial Agreement
- If advertisements and/or questionnaires/prompts are to be used for the clinical or other investigation involving human subjects, these must also be approved by the EAG prior to use thereof.

All Interactions are to be held virtually.

Responsible person		Action to be taken
EAG Secretariat	1	Receive Applications via email

		Assess Application for completeness Send complete application to the chair of the EAG within 3 working days
Chair or designated Deputy	2	Assess the risk level of the application (See SOP 2)
Chair or designated Deputy	3	Assign to reviewers as per risk level
Chair and Assessors	4	Review the protocol and other documents received from the EAG Secretariat in detail.
Assessors and EAG Secretariat	5	The Consent/Participant Information Leaflet is to be checked for compliance with the latest version of the EAG Secretariat Checklist
Assessors	6	Present report on the protocol reviewed from an ethical perspective taking into account the reports from the reviewers who review from a scientific, clinical and safety perspective.
Assessors	7	Timeline for Review.: Reviews are required to be submitted to EAG Secretariat within ten working days from date of receipt
Chairperson	8	Call for vote on approval/non-approval of protocol if all issues relating to the protocol are resolved except for low risks and OR studies
All members	9	Vote on approval/non-approval of each protocol reported on by the Expert Reviewers. The decision of approval must be based on the criteria for approval of research in ICH-GCP . The amount of risk to patients is considered and discussed by the committee with regards to benefit to the patient, potential risk due to the study drug, study procedures, concomitant therapy, concurrent diseases and the potential effect of the study thereon, implications in terms of vulnerable populations.
EAG Secretariat	10	Prepare draft notes of the discussion according to the EAG Secretariat procedures. The notes should contain the following information: • Results of voting by members • Actions taken by the EAG • Written summary of discussion of controversial issues • Resolution of these issues
Chair	11	Review draft notes and make corrections as necessary then forward to EAG Secretariat for finalization.
EAG Secretariat	12	Send approval letters and address unresolved queries with the Investigators and or sponsors as required
EAG Secretariat	13	Ensure that all documentation is archived

5. Informed consent considerations

The informed consent template should in addition,
according to the revised Common Rule, have the following information. The focus of informed consent to the potential subject with:

- Information that a “Reasonable Person” would want in order to make an informed decision;
- Changes to facilitate subject’s understanding of the key reasons he/she would or would not choose to participate in research
- Requirement that Key Information essential to that decision be presented first in the document and consent discussion.

6. ATTACHMENTS

- EAG Secretariat Checklist
  - Checklist for application
  - Informed Consent Checklist

Checklist for application

The submission requirements for the EAG are described below and are presented by way of assistance to all applicants.

Timing of applications

The turn-around time for receipt of the clearance certificate is 28 working days post the meeting, assuming that the proposed research meets all the requirements to be regarded as ethical.

Check List

Please add a tick against each required document:

Document description	✓
Protocol	
Complete ethics application form, including all relevant sections	
- Please check that all forms are signed by the Principal Investigator	
Research tools needed in the study (where appropriate)	
- Questionnaires	
- Interview schedules	
- Information sheets	
- Informed consent form	
- Assent form	
- Data collection sheet	
Approvals and letters of permission	
- Letter of permission to conduct research from other relevant authorities	

Informed Consent Checklist

INFORMED CONSENT FORMS

Principles

- Information Sheets for potential participants should be **brief and understandable** by the people who are being asked to participate in the study
- The information must be provided in the home language of potential participants. An English translation is required for the EAG.
- They must be presented in writing or verbally avoiding medical and technical terms. If there is no alternative, such terms must be explained simply
- Researchers should pre-test the information sheet to see if it is really understood (See the instructions on the Template)

Recommended model

Title of study:

Principal Investigator name:
Address:
Contact number:

You are being invited to take part in a research study. Please take some time to read the information presented here, which will explain details of this study. Please ask the researcher any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Your participation is entirely voluntary and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever, including health care now or in the future. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by ..... (Name the Ethics committees and health authorities who approved), and will be conducted according to ethical guidelines and principles of the International Declaration of Helsinki, as well as local ethical guidelines (.....name these, if any are used)

In addition, the protocol was approved by the Ethics Advisory Group of the International Union against Tuberculosis and Lung Disease

Contact Details of the EAG.

Chair……..
Email Address……..

What is this research study all about?
Explain briefly and simply using bullet points. Avoid medical or technical words. What procedures will be done and where, how long will these take and will return visits will be needed

Why have you been invited to participate?
Explain briefly how potential participants were selected (without detail about sampling processes)

What will your responsibilities be?
List, using bullet points, exactly what the participant will be asked to do, so they know what to expect and can make a decision about whether or not they are prepared to do it.

Will you benefit from taking part in this research?
Explain any possible benefits to individuals

Will photographs be taken or tape recordings made?
Identifiers must be explained and specific consent asked for these procedures

Will audio and video recording be made?
Identifiers must be explained and specific consent asked for these procedures

Are there in risks involved in your taking part in this research?
List any risks and how these will be managed

Who will have access to the results of this study?
Explain briefly and simply how results will be kept confidential

Where can participants get results of the study should they wish to have them?
Provide details of who can provide results

Are there any costs involved and will you be paid to take part in this study?
Explain clearly, including any reimbursements

Do you have any questions about the research?
If there is anything else that you want to know, if you have any further queries or encounter any problems you can contact .....(give name of PI)

You will receive a copy of this information and consent form for your own records.

CONSENT FORMS

Principles

- All study participants must consent to participate voluntarily in a study.
- They must sign that they have received and understood information about the study including what it is about and what is expected of them.
- The permission and collaboration of local civic/tribal leaders and health care providers is an important component of study preparation, although this never replaces individual participant consent.

Consent/Assent in the case of studies on children

- When potential participants are children [as legally defined locally] the consent of the parents or guardians must be obtained in line with local custom and practice.
- A child old enough to understand must agree to participate (assent). If such a child does not wish to participate, even if parents consent, they should not be included.

Recommended model

Declaration by participant

By signing below, I ……..……. agree to take part in a research study entitled ..... (given name of study)

- I declare that:
  - I have read this information and consent form and understand the contents
  - I have had a chance to ask questions and all my questions have been adequately answered
  - I understand that taking part in this study is **voluntary** and I have not been pressurized to take part
  - I may choose to leave the study at any time and will not be penalised or prejudiced in any way

Signed at (*place*) .....…..…….. on (*date*) ……...……...

.....S

Signature of participant (or mark X if cannot sign name)

(Parent/guardian consent section to be added if applicable)

Declaration by researcher

I *(name)* ……..…… declare that:

- I explained the information in this document to ……....
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter (*Sign the declaration below if an interpreter is used)*

Signed at (*place*) ..... on (*date*) ……...……...

.....

Signature of researcher

Declaration by impartial witness/interpreter

I *(name)* ……..…… declare that:

- I assisted the researcher (*name*) ……. To explain the information in this document to (*name of participant*)

  ……..…….. using the language medium of ..... (state which)

- I conveyed a factually correct version of what was related to me
- We encouraged him/her to ask questions and took adequate time to answer them
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her questions satisfactorily answered

Signed at (*place*).....…..……on (*date*) ……...……..

.....

Signature of interpreter