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

STANDARD OPERATING PROCEDURE

SOP-EAG 005 vs1 **IMPLEMENTATION DATE:**

SUBJECT:	**Procedure for the ongoing review of research by the EAG.** **This includes the review of:** ♦ Serious Adverse Events, ♦ Progress Reports, End of Study Reports and Study Termination Reports ♦ Approval of Amendments, Advertisements. ♦ Changes to Participant Information/Consent documents. ♦ Approval of additional Investigators and /or Sites. ***also includes*** ♦ Continuing review (Recertification) of each ongoing trial at intervals appropriate to the degree of risk to human participants.
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 ongoing review of Research on Human Participants in protocols approved.
PREVIOUS VERSIONS / ***(REASON FOR REVISION)***	
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APPROVALS:	**Signature of Chair** **Date:**

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1. DEFINITIONS AND ABBREVIATIONS

CFR	Code of Federal Regulations (USA)
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
SAE	Serious Adverse Event Reports
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
- 21 Code of Federal Regulations Part 56 – Institutional Review Boards
- 21 Code of Federal Regulations Part 50 – Protection of Human Participants

3. PROCEDURE FOR ONGOING REVIEW OF RESEARCH ON HUMAN PARTICIPANTS THAT IS APPROVED BY THE EAG

3.1. Review of Serious Adverse Events, Progress Reports, End of Study Reports and Study Termination Reports

Responsible person		Action to be taken
Two Designated Committee Members	1	Report on SAE findings - Instruct the EAG Secretariat to request safety information and / or comment from Sponsors of studies where there have unexpected frequency of SAE', or 'apparent increase in observed SAE' possible / probable / related causality SAE's and Adverse Drug Reactions (ADR's) reported in a month
All members (To be emailed every quarter)	2	Review list of Serious Adverse Events (SAE's) / ADR's, (compiled in accordance with SOP-EAG-005) amendments passed by the Chairperson, Study Progress Reports, End of Study Reports and Study Termination Reports for the quarter.
	3	Address any issues of concern relating to the above-mentioned list during the EAG meeting and request complete reports of any such documents from the EAG Secretariat as required.
Assessors	4	Assessors should pay particular attention to reports relating to protocols that were reviewed by them.
EAG Secretariat	5	Address any issues brought up by the EAG with the Investigator and/or Sponsor as appropriate and forward responses to the EAG Chair. These issues will then be addressed again in the next quarter.
	6	Track the receipt of progress reports for EAG review on approved research.

3.2. Approval of amendments to clinical investigations and participant information leaflets/consent approved by the EAG.

Investigators are not to implement any amendments until official approval has been received from the EAG unless a change was implemented to eliminate immediate hazards to the participants. In such a case the EAG should be informed of such deviations from the protocol immediately.

3.2.1. Review of minor amendments (expedited review process)

Amendments are considered **MINOR** if they involve administrative changes or changes that do not affect the safety of patients or the conduct and safety of the clinical investigation. In the case of a minor amendment an expedited review process is applied. This allows the EAG Chair, or one or more reviewers designated by the Chairperson, to approve such a proposal without requiring a full EAG approval procedure.

Chair (or designated reviewer(s))	1	Review amendment on receipt of the amendment and Amendment Approval Letter from the EAG Secretariat
	2	If no objections are raised, the Amendment Approval letter must be dated, signed and returned to the EAG Secretariat for further distribution to the investigator and sponsor.
	3	If there are objections to approval of the amendment, the amendment and relevant comments must be returned to the EAG Secretariat for resolution of the queries and full EAG approval.
EAG Secretariat	4	Distribute approval letter OR handle queries and forward responses to the EAG Chair for approval as appropriate.
	5	Ensure that all documentation relating to the amendment, and the amendment, are archived according to the relevant procedures.

3.2.2. Approval of major amendments

Two members of the EAG must review amendments that affect the conduct of the clinical investigation and/or human participant's safety. The EAG Secretariat handles administrative issues such as acknowledgement of receipt, and distribution of the amendment to two Committee Members designated by the Chair and the Chairperson. These amendments are to be reviewed and comments forwarded to the EAG Secretariat within one week for distribution to the investigator and sponsor.

Chair	1	Designate one member OR the original Ethics Assessor / Reviewer of the EAG to co-review the Amendment.
	2	If the reviewers, without any queries, approve amendment, the Amendment Approval Letter must be signed when obtained from the EAG Secretariat. The EAG Secretariat will issue an approval in writing. .
	3	Return approval letter to the EAG Secretariat for further distribution to the investigator and sponsor.
EAG Secretariat	4	Address any queries arising from the reviewers with the investigator and sponsor until resolution thereof. Once all issues are resolved, the Chair approves the amendment.
	5	Distribute Amendment Approval Letter according to the relevant procedure
	6	Send a copy of the Amendment Approval Letter and any relevant correspondence for archiving according to the relevant procedure.

3.2.3. Approval of additional investigators/co-investigators and/or sites (expedited review process)

Chairperson	1	Review request for new Investigator/Site. Additional Investigators/Sites may be approved according to the Expedited Review process. A copy of the new/additional Investigator CV detailing the trial experience of the new/additional Investigator to be submitted with the application. This must be accompanied by

		a copy of the certificate obtained by the new/additional Investigator attending a recognised GCP course and Ethics Training course. This allows the EAG Chairperson, or one or more reviewers designated by the Chair to approve such a proposal without requiring a full EAG approval procedure.
	2	If no objections are raised, the Request for new/additional Investigator/Site approval letter must be signed and returned to the EAG Secretariat for further distribution to the Investigator and Sponsor.
	3	If there are objections to approval of the new Investigator and/or Site, the EAG Secretariat must be notified of the objections
EAG Secretariat	4	Ensure that all documentation relating to the new/additional Investigator/Site, are archived according to the relevant Secretariat procedures

3.3. The approval and ongoing review of clinical trials by the EAG

The requirements of the applicable ICH GCP FDA Code of Federal regulations will be applied in considering approval of Protocols and Informed Consent/Participant Information Leaflets. The EAG will review all payments to be made to participants to assess possible problems with coercion or undue influence on participants.

So as to facilitate the ongoing review of the clinical investigations that were approved, reports containing the following information are required on a regular basis from the Investigator:

- Number of Participants recruited
- Summary description of participants experiences (benefits, adverse reactions)
- Number of withdrawals and reasons for withdrawal
- Complaints
- Results obtained to that point
- Risk-benefit ratio based on results
- Any new information obtained since the EAG's most recent review

All Serious Adverse Events and Adverse Drug Reactions must be reported as per the requirements of the EAG to ensure ongoing approval of the trial.

We hereby confirm that the EAG Approval Granted for a study is VALID FOR FIVE YEARS. Where required by the Sponsor to have recertify a study on a more frequent basis it remains the responsibility of the Sponsor and Investigator to apply for continuing review and approval, or for the duration of the trial.