

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

STANDARD OPERATING PROCEDURE

SOP-EAG 004 vs1

IMPLEMENTATION DATE:

SUBJECT:	Procedure regarding management of any compliance queries and/or deviations										
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 relating to identified queries and/or deviations regarding Clinical Trials that are approved by the EAG										
PREVIOUS VERSIONS / (REASON FOR REVISION)	N/A										
CONTENTS:	<table border="0"> <tr> <td>1. DEFINITIONS AND ABBREVIATIONS</td> <td align="right">1</td> </tr> <tr> <td>2. REFERENCES</td> <td align="right">1</td> </tr> <tr> <td>3. OVERALL POLICY STATEMENT</td> <td align="right">2</td> </tr> <tr> <td>3.1. QUERY/DEVIATION IDENTIFIED BY EAG</td> <td align="right">2</td> </tr> <tr> <td>3.2. QUERY/DEVIATION IDENTIFIED BY SPONSOR</td> <td align="right">2</td> </tr> </table>	1. DEFINITIONS AND ABBREVIATIONS	1	2. REFERENCES	1	3. OVERALL POLICY STATEMENT	2	3.1. QUERY/DEVIATION IDENTIFIED BY EAG	2	3.2. QUERY/DEVIATION IDENTIFIED BY SPONSOR	2
1. DEFINITIONS AND ABBREVIATIONS	1										
2. REFERENCES	1										
3. OVERALL POLICY STATEMENT	2										
3.1. QUERY/DEVIATION IDENTIFIED BY EAG	2										
3.2. QUERY/DEVIATION IDENTIFIED BY SPONSOR	2										
APPROVALS:	<table border="0"> <tr> <td align="center">Signature of Chairperson</td> <td align="right">Date:</td> </tr> </table>	Signature of Chairperson	Date:								
Signature of Chairperson	Date:										

1. DEFINITIONS AND ABBREVIATIONS

GCP	Good Clinical Practices
ICH	International Council for Harmonisation
EAG	Ethics Advisory Group

2. REFERENCES

- ◆ ICH Harmonised 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

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

STANDARD OPERATING PROCEDURE

SOP-EAG 004 vs1

IMPLEMENTATION DATE:

♦

3. Overall policy statement

The EAG aims to manage any queries and/or deviations regarding research including Clinical Trials identified for any research activity conducted by the Union staff or consultants

The EAG Secretariat will handle all administrative functions of the EAG.

3.1. QUERY/DEVIATION IDENTIFIED BY EAG

Any deviation from the principles and guidelines of good clinical practice and/or the protocol can be reported to the EAG by

- Participants on a study
- Relatives, friends, acquaintances of participants on a study
- Community Advisory Boards
- Department or Ministry of Health
- Any interested parties

The EAG can request a written report responding to questions raised,

These deviations will be examined by a Chair and if necessary will be put before the EAG for action. This action may include sending an EAG monitor or an independent auditor to the site. For this reason, the contact details of the secretariat of the EAG must be on all informed consents of studies approved by the EAG.

Where deemed necessary by the EAG and the Sponsor Company (if applicable) the EAG will appoint and send an independent auditor/EAG monitor or a member of the EAG to the problem site for an audit/monitoring visit dependent on the nature of the problem. This type of monitoring may be conducted by a partner of the Union including but not limited to MSF. The audit/monitoring visit findings will be reported to the EAG. Upon receipt of the findings, the EAG may set up a meeting with the appropriate sponsor company to discuss correctional measures to be implemented.

The actions may include that may include, but not be limited to, disqualification as an investigator and rehabilitation before being accepted as an investigator in other studies.

Depending on the severity of the deviation, Investigators will either attend a meeting convened via Skype or similar platform the Chair of the EAG and a representative from the EAG Secretariat, or be required to address the full EAG Committee at a virtual meeting of the Committee. The Sponsor Company will, as a matter of course be informed of the meeting and may also attend the meeting if they choose to do so.

Should it be deemed necessary, a site might be disqualified from future clinical research until appropriate rehabilitation has taken place.

3.2. QUERY/DEVIATION IDENTIFIED BY SPONSOR

Should a sponsor company identify a problem at an EAG trial site (protocol deviation/violation), this should be communicated to the EAG Secretariat as soon as possible after identification, who will refer the matter to the Chairperson. The communication will be examined by the Chairperson and if **necessary**, this will be put before the Ethics Committee for noting or action.

All protocol deviations where patient safety, data integrity or regulatory compliance is compromised needs to be notified to the EAG immediately once known.

Investigators are urged to review all deviations and report deviations where the consequence has a negative impact on the study and where they feel the EAG needs to be aware of this.

Where deemed necessary by the EAG, an independent auditor / EAG monitor will be appointed and sent to the problem site for an audit/monitoring visit dependent on the nature of the problem. The audit/monitoring visit findings will be reported to the EAG. Upon receipt of the findings, the EAG may

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

STANDARD OPERATING PROCEDURE

SOP-EAG 004 vs1

IMPLEMENTATION DATE:

set up a meeting with the appropriate sponsor company to discuss correctional measures to be implemented.

Should it be deemed necessary, a site might be disqualified from future clinical research until appropriate rehabilitation has taken place.

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

STANDARD OPERATING PROCEDURE

SOP-EAG 004 vs1

IMPLEMENTATION DATE:
