

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

**STANDARD OPERATING PROCEDURE**

**SOP-EAG 007 vs1**

**IMPLEMENTATION DATE:**

<b>SUBJECT:</b>	<b>Management of Standard Operating Procedures</b>	
<b>DIVISION / SCOPE:</b>	<b>International Union against TB and Lung Disease Ethics Advisory Group (EAG)</b>	
<b>AUTHOR: REVISION:</b>	<b>EAG Secretariat</b>	
<b>PURPOSE:</b>	<b>This procedure describes the process to be followed by the EAG relating to frequency and type of review of Standard Operating procedures.</b>	
<b>PREVIOUS VERSIONS / (REASON FOR REVISION)</b>	N/A	
<b>CONTENTS:</b>	<b>1. DEFINITIONS AND ABBREVIATIONS</b>	<b>1</b>
	<b>2. REFERENCES</b>	<b>1</b>
	<b>3. OVERALL POLICY STATEMENT</b>	<b>1</b>
	<b>4. LIST OF REQUIRED SOPS</b>	<b>2</b>
	<b>5. SUGGEST TEMPLATE FOR SOPS</b>	<b>3</b>
<b>APPROVALS:</b>	<b>Signature of Chairperson</b>	<b>Date:</b>

**1. DEFINITIONS AND ABBREVIATIONS**

GCP	Good Clinical Practice
ICH	International Council for Harmonisation
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](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&pid=20180719&n=pt45.1.46&r=PART&ty=HTML>

**3. Overall policy statement**

In order for the EAG to retain an institutional memory, ensure sustainability and transparency there is a need for written Standard Operating Procedures. These SOPs must reflect the most current version of the guiding principles of research including but not limited to

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- ◆ ICH Harmonized Guideline
- ◆ Declaration of Helsinki
- ◆ 45 Code of Federal Regulation 46 (Common Rule)
- ◆ Country Based Good Clinical Practice guidelines if applicable

These SOPS need to be posted on the Union's website. In addition, these SOPS needs to be reviewed on an annual basis by the secretariat and approved by the Chair. Any changes and the reasons for these changes need to be recorded. (SOP EAG POLICY 7)

**4. List of required SOPs**

- 4.1. Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution (SOP EAG POLICY 1)
- 4.2. Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and
- 4.3. Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject. (SOP EAG POLICY 2, SOP EAG POLICY 5)
- 4.4. Establish and follow written procedures for ensuring prompt reporting to the EAG; appropriate institutional officials( SOP EAG POLICY 4)
- 4.5. The procedure describing the process to be followed for the election of members, training and qualification of members and terms of office (SOP EAG POLICY 3)
- 4.6. SOP SAG POLICY 6 describes how Serious Adverse Events should be reported
- 4.6.3. Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB (SOP EAG POLICY 5)
- 4.6.4. Any suspension or termination of IRB approval (SOP EAG POLICY 5)

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**5. Suggest Template for SOPs**

SUBJECT:	Procedure regarding
DIVISION / SCOPE:	
AUTHOR: REVISION:	
PURPOSE:	This procedure describes the process to be followed by the EAG relating to identified queries and/or deviations regarding Clinical Trials that are conducted by the Union or its employees
PREVIOUS VERSIONS / (REASON FOR REVISION)	
CONTENTS:	
APPROVALS:	Signature of Chairperson  Date:

**DEFINITIONS AND ABBREVIATIONS**

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

**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

**Overall policy statement**

**DEFINITIONS AND ABBREVIATIONS**

**Some examples**

FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
IRB	
EAG	

**REFERENCES**

**ATTACHMENT**