

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

STANDARD OPERATING PROCEDURE

SOP-EAG 003 vs1

IMPLEMENTATION DATE:

SUBJECT:	EAG membership												
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 for the election of members, training and qualification of members and terms of office												
PREVIOUS VERSIONS / (REASON FOR REVISION)	N/A												
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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 (ICH GCP term)

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
- US 45 CFR 46 (The Common Rule)

3. EAG Composition

The EAG shall have at least five members.

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There must be a chair and a designated deputy chair with equal powers to the chair who may act in the absence of the chair.

These members must have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the Union, and there should be 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. In addition, due to the diverse locations of the work of the Union, there should also be geographical representation in the membership of the EAG.

EAG members should be sufficiently qualified through the experience and expertise. In addition to possessing the professional competence necessary to review the specific research activities, the EAG should be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The EAG shall therefore include persons knowledgeable in these areas.

The EAG may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the EAG. These individuals may not vote with the EAG.

The EAG must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. This should include, one member has had an international development/social science background, with an interest in ethics, for diversity of perspective

The EAG must include at least one member who is not otherwise affiliated with the International Union Against TB and Lung Disease and who is not part of the immediate family of a person who is affiliated with the institution.

THE EAG may not have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The member must recuse themselves from the discussion.

All of the above criteria are contained in the Common Rule. All research conducted with United States federal funding must comply with all of these.

4. Term of Office of EAG members and election procedures.

Each member may serve two terms of 3 years each. In exceptional cases, this may be extended to three. Each member must rotate off the group for at least a year after two terms of office and would then be eligible to re-election.

The Union will put out a call for potential applicants for the EAG every two to three years, and as dictated by additional vacancies arising.

All suitable applicants' CV's will be reviewed by the current chair as well as an independent person from the Union office. Suitable candidates will be shortlisted and will be invited for an interview. Curriculum vitae will be distributed to EAG members for prospective new members by the Chair. The prospective candidates will be discussed virtually by the EAG following their agreement to stand for EAG membership. Once the EAG members have agreed on the new EAG member, a curriculum vitae and motivation are sent by the Chair to the Union Bureau.

The proceeding will be transparent with the successful candidate's names, qualification and start date being posted on the Union's website.

Research Ethics Training is a compulsory requirement for all members of the EAG. The following are suggested

- Training and Resources in Research Ethics Evaluation (TRREE). A suitable module is <https://elearning.trree.org/>: Introduction to research ethics

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- The Citi Program has a similar course. However, there is a cost implication and their material tends to be more US based. <https://about.citiprogram.org>

The responsibility of the approving specific ICH GCP training rests with the chair of the EAG.

Documentation of successful completion of a training program must be filed with the members' CV.

5. Publication of information on members

The secretariat should prepare and maintain a current list of the EAG members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to EAG deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. This should be a matter of public record and should be posted on the website of the Union. A suggest template the members CV is contained in the below.

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6. Template for CV

EAG format membership	
1. Personal Details	
Name:	
Work Address:	
Telephone Number:	
Fax Number:	
Cell-phone Number:	
e-mail address:	
2. Academic and Professional Qualifications	
Institution:	
Degree(s)/Diploma(s):	
Year Completed:	
3. Professional Statutory body registration number (if applicable)	

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<p>4. Relevant related work experience (brief) and current position</p>
<p>5. Peer-reviewed publications in the past 3 years</p>
<p>6. Date of last Ethics training</p> <p>Ethics Course Provider:</p> <p>Discipline:</p>
<p>7. Any additional relevant information supporting abilities to participate in EAG [briefly]</p>
<p>8. Signature:</p> <p>Date:</p>