## Policies and Standard Operating Procedures – Ethics Advisory Group consultancy

**The International Union Against Tuberculosis and Lung Disease (The Union**) is an international scientific organisation headquartered in Paris, France, with region and country offices in Africa, Asia Pacific, Europe, Latin America, North America and South-East Asia. The focus of our work is on tuberculosis and lung disease, as well as related challenges such as HIV and tobacco control, with emphasis on their impact in low- and middle-income countries.

Since our founding as a global scientific organisation in 1920, The Union has drawn from the best evidence and the skills, expertise and reach of our staff, consultants and membership in order to advance solutions to the most pressing public health challenges affecting people living in poverty around the world.

As a scientific organisation, The Union's approach starts with evidence. We conduct research so that we can know the nature of the challenges we face and their most effective solutions. Through our peer-reviewed journals, our global and regional conferences, and through training courses and technical assistance, we provide platforms for sharing scientific knowledge with stakeholders around the world. And by directly delivering health services and advocating on behalf of those affected by tuberculosis and lung disease, we directly act on the best available scientific knowledge. Know. Share. Act. These principles have driven The Union's work since its founding.

For more information about The Union, please visit www.theunion.org

### Background

The Ethics Advisory Group (EAG) was established to provide ethical guidance on The Union's work at national and international levels. Its role is to safeguard the dignity and rights of study participants and to promote ethical standards in lung health services. The EAG is made up of six to eight Union members, who are selected to ensure not only professional and geographic diversity, but also representation of low-income countries and community groups. Current members are citizens of South Africa, India, Sudan, Australia, Ethiopia and the USA. They are professionals in the fields of social science, research, clinical medicine and public health.

The EAG applies the standards set out in ICH Harmonised Tripartite Guideline for Good Clinical Practice E6 (GCP). In addition, the EAG is an Institutional Review Board registered with the United States Office for Human Research Protection (OHRP) (IRB00002330; see https://ohrp.cit.nih.gov/search/IrbDtl.aspx).

In connection with an internal review of the EAG's policies, procedures and practices, the EAG is seeking a consultant with significant expertise regarding the GCP and OHRP requirements applicable to ethics committees and institutional review boards.

**Scope of work**

The consultant will undertake a comprehensive review of the EAG's policies and standard operating procedures as they relate to EAG membership, governance and initial and continuing review of research studies in order to ensure compliance with the GCP and OHRP requirements. Where revisions to the EAG's policies and SOPs are required, the consultant will lead the process, working with the EAG Chairman, of drafting and implementing the revised policies and SOPs.

As a separate activity that would only be undertaken as/when requested by the EAG, the consultant may be asked to conduct one or more training sessions regarding the revised policies/SOPs.

**Deliverables and target delivery dates**

| Deliverable | Target delivery date |
|---|---|
| Written report on policies and SOPs of the EAG containing recommendations | Start + 1 month |
| First draft of revised policies and SOPs | Start + 2 months |
| Final draft of revised policies and SOPs | Start + 3 months |
| Training on revised policies and SOPs (if requested by EAG) | As mutually agreed by consultant and EAG |

**Qualifications and experience**

The consultant will have significant experience in the management and oversight of multi-site clinical trials, at both US and non-US sites, including:

- MD or Master's degree (or higher) in public health or another relevant discipline
- Experience with the ICH Good Clinical Practice Guidelines, as they relate to institutional review boards/ethics committees (IRBs)
- Experience with the US Common Rule, as it relates to IRBs
- Experience reviewing/developing policies and standard operating procedures
- Experience as a member of/advising IRBs preferred
- Experience managing and implementing multi-site clinical trials preferred

**How to apply**

Please send your CV and a cover letter including your expectations to hr@theunion.org

The position will be open until the candidate has been selected for the post. Only shortlisted candidates will be contacted.