

Experts Meeting
The “*Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials*” pathways to implementation

June 6th, 2025

**European Commission, Square Frère-Orban 8, Brussels, Belgium
RTD ROOM ORBN 05/A066**

Objectives

This one-day meeting aims at discussing how to improve research policy and ethics review processes to optimize the protection of healthy volunteers involved in clinical research.

Our primary focus will be on European countries, but broader perspectives will be welcomed.

A key point of discussion will be to assess how the conclusions and recommendations of the VoIREthics “**Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials**” can be implemented in the context of research ethics review processes to contribute to an improved protection of healthy volunteers. Furthermore, concrete pathways to implementation as well as potential barriers will be discussed from the point of view of a variety of stakeholders, in particular: research funding agencies, ethics review committees, study sponsors from the private and public sectors, regulatory agencies, private and public investigators. Specific attention will be given to the implications and lessons for the EU Ethics appraisal process and relevant reporting guidelines (clinical study package).

Scientific Committee: Cristine Chiotan, François Bompert, Yves Donazzolo, François Hirsch, Lorenzo Montrasio, Shadreck Mwale

Organizing Committee: Cristine Chiotan, François Bompert, François Hirsch, Christine Lemaitre, Edyta Sikorska

Agenda

10:00 to 10:30 – Opening

- Yves Dumont, Cristina Chiotan, Ethics Sector, DG RTD
- Hervé Chneiweiss, Chair of Inserm Ethics Committee (France)
- François Hirsch, Inserm Ethics Committee (France)
- Shadreck Mwale, (VolREthics & Univ West London, UK): overview of findings on Healthy Volunteers to set the scene

10:30 to 11:30 – Ethics Review Committees’ Roundtable – What pathways to implement the best protection standards for Healthy Volunteers? What role for the Global Ethics Charter?

Facilitator: Shadreck Mwale (VolREthics & Univ. of West London, UK)

Panelists: Monique Al (MedEthics EU); Jane Bryant (National Office of Research Ethics Committees, Ireland); Mariagrazia Di Marco (Clinical Ethics Center, Univ. of Geneva, Switzerland); Tomas Dolezal (Council of Europe); Virginie Rage-Andrieu (Association of CPP-CNCP, France); Christel Vansteenkiste (Belgian Association of Research Ethics Committees)

Q&A: 25 minutes

15 minutes COFFEE BREAK

11:45 to 12:45 – Regulators Roundtable – What pathways to implement the best protection standards for Healthy Volunteers? What role for the Global Ethics Charter?

Facilitator: Lorenzo Montrasio (VolREthics & Office against racial discrimination, Italy)

Panelists: Luc Bigel (DLA Piper, France); Nicola Burgess (HRA, UK); Nina Hulin (Ansm, France); Sandra Petraglia (AIFA, Italy)

Q&A: 25 minutes

45 minutes LUNCH BREAK

13:30 to 14:45 – Private and public sponsors and investigators’ Roundtable – What pathways to implement the best protection standards for Healthy Volunteers? What role for the Global Ethics Charter?

Facilitator: Yves Donazzolo (VolREthics & Eurofins Optimed & EUFEMED, France)

Panelists: Jérôme Fabiano (EIT-Health); Naheeda Hamza (Univ. of Oslo, Norway); Jean-Daniel Lelièvre (AP-HP, France); Franck Letellier (GSK); Erik Rein-Hedin (CTC, Sweden); Nathalie Sloomans (Pfizer); Marta Zakrzewska (PRATIA, Poland)

Q&A: 20 minutes

15 minutes COFFEE BREAK

15:00 to 16:30 – General discussion: how to move forward together to better protect Healthy Volunteers in Europe and globally?

Facilitator: François Bompert (Inserm Ethics Committee & DNDi)

Panelists: Frédéric Arénou (France); Maria-Filipa Ferraz-de-Oliveira (ERCEA); Dafna Feinholz (UNESCO); Silvia Garcia (EDCPT3JU);

16:30 – Adjourn

Hervé Chneiweiss, Mihalis Kritikos (European Group on Ethics)