



<https://www.inserm.fr/en/ethics/volrethics/>
<https://europa.eu/sinapse/directaccess/hvguidance>

How to protect Healthy Volunteers from Exploitation in Biomedical Research?

CURRENT AGENDA

5th online regional seminar: focus on Europe
Friday January 27th, 2023
10:00am to 12:30pm Paris/Brussels/Bonn time

The meeting will be recorded

PURPOSE: The VolREthics international initiative on ethical issues related with healthy volunteers' involvement in biomedical research was launched by the Ethics Committee of the French National Institute for Health and Medical Research (Inserm). A first international meeting, held online in February 2022 from UNESCO premises in Paris, identified research situations where the rights, well-being and safety of healthy volunteers may be jeopardized. Building on this first meeting, regional seminars are now being organized with two primary purposes:

- ✓ to update our knowledge on the scientific and ethical issues in specific regions of the world,
- ✓ to build a repository of new insights and policy recommendations to safeguard the rights, well-being and safety of healthy volunteers globally.

To date, regional seminars have been organized for Africa, Asia, North America and Latin America.

SCOPE: Focusing on Europe, this 5th regional seminar will be co-hosted by the Ethics Sector of DG Research & Innovation of the European Commission, the European Network of Research Ethics Committees (EUREC) and the Ethics Sector of the European Research Council Executive Agency (ERCEA). Real-life situations experienced by attendees from Europe, including that of **healthy volunteers** will be presented.

→ **The VolREthics Initiative –Framework and initial steps (10:00 – 10:15 am)**

François Bompard (*Drugs for Neglected Disease initiative, Inserm Ethics Committee*)

→ **Introduction by the co-chairs (10:15 – 10:30 am)**

Lisa Diependaele (*Ethics Sector, DG Research & Innovation, European Commission*)

Filipa Ferraz-de-Oliveira (*Ethics Sector, European Research Council Executive Agency, European Commission*)

→ **How to protect HVs from exploitation: European perspectives. 10:30 – 11:15)**

Moderator: Dirk Lanzerath (*European Research Ethics Committees network- EUREC*)

Set the scene:

- Antigone Dimas (*Biomedical Sciences Research Centre Alexander Fleming, Greece*)

- Renke Maas (*Friedrich-Alexander-Universität, Germany*)

- Ivan Vyshnivetsky (*President of the Ukrainian Association for Clinical Research / Managing Director Ukraine at FutureMeds*)

→ **Experiences of European Healthy Volunteers (11:15 – 11:45)**

Moderator: François Hirsch (*Inserm Ethics Committee*)

→ **Open discussion with the audience: identified risks of exploitation, field experiences, recommendations (11:45 – 12:15)**

Moderator: Alexandra Rolaki (*Ethics Sector, European Research Council Executive Agency, European Commission*)

Sharing experiences:

- Laurențiu Staicu (*Universitatea din Bucuresti, Romania*)

- Roman Fishchuk (*Clinical trials department at Central City Clinical Hospital, Ukraine*)

- Thomas Hinault (*Neuropsychology and Imaging of Human Memory Unit, Inserm, France*)

- Aneta Sitarska Haber (*Polish Association for Good Clinical Practice (GCPpl)*)

- Shadreck Mwale (*West London Univ., UK*)

→ **Concluding Remarks (12:15 – 12:30)**

Dirk Lanzerath (*European Research Ethics Committees network- EUREC*)

François Eisinger (*Inserm Ethics Committee*)

To register: please send message to hyworkshop.disc@inserm.fr