



VolREthics

Volunteers in Research and Ethics initiative



Towards Ethical Guidance to Protect Healthy Volunteers in Biomedical Research



Inserm

How to protect Healthy Volunteers from Exploitation in Biomedical Research?

Online regional seminar: focus on North America

Save the date

October 19, 2022

10:00am to 12:00pm New York time

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 in February 2022 at UNESCO Paris premises, identified research situations where the rights, well-being and safety of healthy volunteers (HV) may be jeopardized and it identified good practices implemented in some countries to address these issues.

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, and to build a repository of new insights and policy recommendations to safeguard the rights, well-being and safety of HV globally.

SCOPE: Focusing on North America, this regional seminar will be hosted by the CMORE (The Comparative Model Organism Research Ethics) for Healthy Volunteers Project and the University of North Carolina Center for Bioethics. It will include discussions on real-life situations experienced by attendees from the USA and Canada, including that of **healthy volunteers from the USA. Please note that the meeting will be recorded.**

DRAFT AGENDA (times in New York time zone)

→ **The VolREthics Initiative - Learnings from the first plenary meeting (10:00 – 10:10 am)**
François Bompard (*Drugs for Neglected Disease initiative*)

→ **Introduction by the co-chairs and overview of the HealthyVOICES and CMORE projects (10:10 – 10:25 am)**

Jill A. Fisher & Rebecca L. Walker (*University of North Carolina at Chapel Hill*)

→ **Exploitation in North American Healthy Volunteer Research: Ethical and Practical Considerations (10:25 – 11:00)**

Trudo Lemmens (*University of Toronto, Canada*)

Seema Shah (*Northwestern University, USA*)

Roberto Abadie (*University of Nebraska, USA*)

→ **Experiences of North American Healthy Volunteers: Phase I Drug Trials and Controlled Human Infection Studies (11:00 – 11:20)**

→ **Open discussion with the audience: identified risks of exploitation, field experiences, recommendations (11:20 – 11:50)**

<https://europa.eu/sinapse/directaccess/hvguidance>

→Concluding Remarks (11:50 - 12:00)

Jill A. Fisher & Rebecca L. Walker (*University of North Carolina at Chapel Hill*)

François Hirsch (*Inserm Ethics Committee*)

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