



Second plenary meeting of the Volunteers in Research and Ethics (VoREthics) Initiative

24-25 April 2023

Covent Garden (COVE) building, Place Rogier 16, 1210 Brussels

A2 – Auditorium 4-15 (4th floor)

DAY 1 – 24 April 2023 – 09:30 to 17:30 CET

Welcome Addresses

09:30 – 09:40 10 min	Hervé CHNEIWEISS , Chair of the Institut national de la santé et de la recherche médicale (INSERM) Ethics Committee (France)
09:40 – 09:50 10 min	Irene NORSTEDT , Director, Directorate D People, DG Research & Innovation (R&I), European Commission
09:50 – 10:00 10 min	François HIRSCH , INSERM Ethics Committee (France)

SESSION 1 – Healthy volunteers' involvement in research projects

10:00 – 10:05 5 min	<i>Introduction by the Chairs</i> Maria-Filipa FERRAZ-DE-OLIVEIRA , European Research Council Executive Agency (ERC) & Dirk LANZERATH , European Network of Research Ethics Committees (EUREC)
10:05 – 10:20 15 min	<i>Healthy volunteers in interventional biomedical research</i> Ingrid KLINGMANN , EUFEMED and European Forum for Good Clinical Practice (EFGCP)
10:20 – 10:35 15 min	<i>Healthy volunteers in human and social sciences research</i> Juliet MWANGA , Epicentre Uganda Research Centre (Uganda)
10:35 – 10:50 15 min	<i>Healthy volunteers and decentralised clinical trials: examples and points to consider</i> Pierre-Henri BERTOYE , MOH CNRIPH (France)
10:50 – 11:00 10 min	Q&A
11:00 – 11:20 20 min	Coffee Break



SESSION 2 – VoREthics progress to date

11:20 – 11:25

5 min

Introduction by the Chairs

Montserrat BLASQUEZ-DOMINIGO, European and Developing Countries Clinical Trials Partnership, EDCTP2 Programme & **Virginie RAGE-ANDRIEU**, Conférence Nationale des Comités de Protection des Personnes (CNCP) (France)

11:25 – 11:55

30 min

Healthy volunteers testimonies

- **Rogers ANKUNDA** (Uganda)
- **John BURWELL** (USA)
- **Kaviya MANOHARAN** (India)
- **Muhamad Haziq Bin MOHD MARPHY** (Malaysia)
- **Bridget TAREMWA** (Uganda)

11:55 – 12:05

10 min

Report of the first plenary meeting

François BOMPART, Drugs for Neglected Diseases Initiative (DNDi) (Switzerland) & INSERM Ethics Committee (France)

12:05 – 12:55

50 min

Reports of the regional meetings

- **Elisabeth ALLEN**, University of Cape Town & TGHN (South Africa) & **Esperança SEVENE**, Eduardo Mondlane University (Mozambique): *Report of the Africa meeting*
- **Nandini KUMAR**, Forum for Ethics Review Committees (India) & **Chun Keat CHEW**, Institute for Clinical Research (Malaysia): *Report of the Asia meeting*
- **Jill FISHER**, University of North Carolina (USA): *Report of the North America meeting*
- **Danilo Cesar GALINDO BEDOR**, Federal University of Pernambuco (Brazil): *Report of the Latin America meeting*
- **Lisa DIEPENDAELE**, Ethics and Research Integrity Sector, DG Research & Innovation, European Commission & **Alexandra ROLAKI**, European Research Council Executive Agency (ERCEA): *Report of the Europe meeting*

SESSION 3 – Breakout sessions to discuss good practices

12:55 – 13:05

10 min

Introduction to the parallel breakout sessions

François EISINGER, INSERM Ethics Committee (France)

13:05 – 14:30

1h25 min

Group photo, working lunch and continued discussion



14:30 – 16:00

1h30 min

Breakout session 1: Protection from exploitation (1)

Chairpersons: **Hélène ESPEROU**, INSERM (France) & **Shadreck MWALE**, University of West London (UK)

Focus on:

- Informed consent processes and documents tailored to volunteers' needs and vulnerabilities
- Processes to determine fair amounts of compensation
- Management of study completion bonuses vs. right to withdraw

Breakout session 2: Protection from exploitation (2)

Chairpersons: **Roberto ABADIE**, University of Nebraska-Lincoln (USA) & **Nadina STADLER**, Independent consultant (Germany)

Focus on:

- Permitted means of recruitment of healthy volunteers
- Standards to ensure well-being during the study
- Information of healthy volunteers on study findings

Breakout session 3: Protection from harm and ensuring validity of studies (1)

Chairpersons: **Janet MIFSUD**, University of Malta (Malta) & **Bram RAMJIWAN**, University of Manitoba & St. Boniface Hospital, Winnipeg (Canada)

Focus on:

- Adapted Institutional Review Boards and study review processes
- Accreditation and inspection of investigators and investigational sites
- Representativity of healthy volunteers for target populations

Breakout session 4: Protection from harm and ensuring validity of studies (2)

Chairpersons: **Lorenzo MONTRASIO**, Council of Europe & **Craig TIPPLE**, Drugs for Neglected Diseases Initiative (Switzerland)

Focus on:

- Healthy volunteers' registries
- Management of incidental findings
- Insurance coverage for adverse events occurring during and after the study (topic introduced by **Luc BIGEL**, DLA Piper France LLP)

16:00 – 16:30

30 min

Coffee break & Consolidation of breakout sessions recommendations

SESSION 4 – Keynote Lecture

16:30 – 17:00

30 min

Jerome SINGH, South African Medical Research Council (South Africa)

Introduced by **Elisabeth ALLEN**, University of Cape Town & TGHN Africa (South Africa)

17:00 – 17:30

30 min

Q&A and discussion



DAY 2 – 25 April 2023 – 09:00 to 18:00 CET

SESSION 5 – Reporting of breakout sessions

09:00 – 09:10

10 min

Welcome & introduction by the Chairs

Jill FISHER, University of North Carolina (USA) & **James A HOUGHTON**, National University of Ireland, Galway (Ireland)

09:10 – 10:40

1h30 min

Reports of the breakout-sessions

1. Protection from exploitation (45 minutes, including Q&A)
2. Protection from harm and ensuring validity of studies (45 minutes, including Q&A)

10:40 – 11:00

20 min

Coffee break

SESSION 6 - Roundtable discussions

11:00 – 12:00

60 min

Roundtable 1: Relevance of proposals made for non-pharmaceutical biomedical research areas

Chairpersons: Fabrice GZIL, Espace Éthique Ile-de-France (France) & **Esperança SEVENE**, Eduardo Mondlane University (Mozambique)

Panellists:

- **Thomas HINAULT**, INSERM (France): *Social sciences*
- **Simon KOLSTOE**, University of Portsmouth (UK): *Controlled Human Infection Models*
- **Thérèse MURPHY**, European Group on Ethics and New Technologies (EGE) & Queen's University Belfast (UK): *Medical Devices*
- **Juliet MWANGA**, Epicentre Uganda Research Centre (Uganda): *Epidemiology*
- **Raffaella RAVINETTO**, Institute of Tropical Medicine, Antwerp & Médecins Sans Frontières (Belgium): *IRB Chair*

12:00 – 13:00

60 min

Roundtable 2: Study sponsors and CROs

Chairpersons: Ignasi BELDA, EIT Health ELSI Board (Spain) & **Henri CAPLAIN**, Association Française de Pharmacologie Translationnelle (AFPT) (France)

Panellists:

- **Deepa ARORA**, CLINEXEL (India)
- **Pierre-Henri BERTOYE**, UNICANCER (France)
- **Yves DONAZZOLO**, European Federation for Exploratory Medicines Development (EUFEMED) and the European CRO Federation (EUCROF)
- **Tatjana POPLAZAROVA**, GSK (Belgium)
- **Nathalie SLOOTMANS**, Pfizer (Belgium)
- **Marta ZAKRZEWSKA**, GCPpl Association and PRATIA S.A. (Poland)



13:00 – 13:50 50 min	Lunch
13:50 – 15:00 70 min	Roundtable 3: Regulatory agencies Chairpersons: Pierre DEMOLIS , Agence Nationale de Sécurité du Médicament et des produits de santé (France) & Trudo LEMMENS , University of Toronto (Canada) Panellists: <ul style="list-style-type: none"> - Maria-Antonietta ANTONELLI, European Medicines Agency (EMA) - Calvin BERTRAND, Direction Générale de la Santé (France) - Natalie KLEIN, Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services (USA) - Nicholas C.W LEOW, National Pharmaceutical Regulatory Agency (NPRA) (Malaysia) - Sandra PETRAGLIA, Agenzia Italiana del Farmaco (AIFA) (Italy) - Tohlang SEHLOLO, South African Health Products Regulatory Authority (SAHPRA) (South Africa)
15:00 – 15:15 15 min	Coffee break
SESSION 7 – Open discussion	
15:15 – 16:00 45 min	<i>Open discussion, including topics for further work</i> Discussion moderated by: <ul style="list-style-type: none"> - Irakli KHODELI, UNESCO - Carleigh KRUBINER, Wellcome Trust (UK) - Pierre MALLIA, European Group on Ethics and New Technologies (EGE) & Health Ethics Committee of the Ministry for Health (Malta)
SESSION 8 – Conclusions & Next steps	
16:00 – 16:30 30 min	<i>Next steps: How to progress in the elaboration of international guidelines for the protection of healthy volunteers globally?</i> <ul style="list-style-type: none"> - Irakli KHODELI, UNESCO - Dominique SPRUMONT, Council for International Organizations of Medical Sciences (CIOMS)
16:30 – 17:00 15 min	<i>Concluding remarks</i> <ul style="list-style-type: none"> - Joanna DRAKE, Deputy Director-General, DG Research & Innovation, European Commission - Hervé CHNEIWEISS, INSERM Ethics Committee (France)
End of day 2	



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