Healthy volunteers have always played a vital role in medical research to serve as controls for patient groups allowing them to define the limits of "normal." They are also required to test new medical strategies, including more or less invasive medical tests, drugs or medical devices. Their role has been exemplified during the COVID-19 pandemic allowing the rapid development of effective vaccines. However, exposing healthy people to unknown risks raises complex ethical issues.

Initiated by a working group of Inserm ethics committee, this meeting aims at paving the way to elaborate an international consensus and guidance in biomedical research involving healthy volunteers. It will allow discussion between the major actors of the biomedical research involving Healthy Volunteers, from the public and private sectors, for profit or not, coming from industrialized countries and from countries with lower economic incomes. Our objectives are, on the one hand, to identify the various research projects that expose these potentially vulnerable participants and on the other hand, through exchanges between the stakeholders gathered, to propose recommendations to allow a comprehensive ethical and responsible management of these researches.

Steering committee

DAY 1 – SETTING THE SCENE
February 15th, 2022

▶ 10H00 – 10H45 • Welcoming remarks
Hervé Chneiweiss
President, Inserm Ethics Committee
François Hirsch
Inserm Ethics Committee
Irakli Khodeli
UNESCO, Bioethics and Ethics of Science and Technology Section

▶ 10H45 – 12H30 • Roundtable 1
Clinical studies with administration of pharmaceutical compounds

Moderator  François Bompart, DNDi

Speakers  Regulatory agencies: Pierre Demolis, Agence Nationale de Sécurité du Médicament et des produits de santé (France)/ European Medicines Agency
Pharmaceutical companies: Mukesh Kumar, Cipla (India) & Aude Le Roux, Sanofi (France)
Contract Research Organisations: Deepa Arora, Clinexel (India) & Nicolas Fauchoux, Biotrial (France/USA)
Q & A

▶ 12H30 – 13H30 • LUNCH BREAK

▶ 13H30 – 14H50 • Roundtable 1 (continued)
Clinical studies with administration of pharmaceutical compounds: Key ethical issues

Moderator  Pierre Mallia, Health Ethics Committee of the Ministry for Health (Malta)

Speakers  Shadreck Mwale, University of West London (UK)
Jill A Fisher, University of North Carolina (USA)
Nandini Kumar, FERCI (India)
Wei Zhu, Shanghai Ethics Committee for Clinical Research (P. R. China)
Q&A

▶ 14H50 – 15H50 • Roundtable 2
Studies in vulnerable populations

Moderator  Tumani Corrah, Africa Research Excellence Fund (Gambia)

Speakers  Emmanuel Baron, Epicentre/MSF
Mukandu Basua Babintu Leyka, Institut supérieur des techniques médicales, Kinshasa (Democratic Republic of Congo)
Samuel Verges, Université Grenoble Alpes (France)
Q&A

▶ 15H50 – 16H05 • BREAK
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<th>16H05 – 17H05 • Roundtable 3</th>
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<td><strong>Human infection challenge studies</strong></td>
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**Moderator**  
Lionel Cavicchioli, *The Conversation (France)*

**Speakers**  
Katherine Littler, *WHO*  
Odile Launay, *Inserm, AP-HP (France)*  
Jonathan Pugh, *University of Oxford (UK)*  
Ingrid Callies, *CCNE (France)*  

**Q&A**

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<th>17h05 – 17h35 • Further steps</th>
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**Moderator**  
Mylène Botbol-Baum, *Inserm Ethics Committee*

**Speaker**  
François Eisinger, *Inserm Ethics Committee*

**Open discussion with all participants**
DAY 2 – DRAFTING RECOMMENDATIONS
February 16th, 2022

► 11H00 – 12H00 • Roundtable 4
Ethical issues raised by non-clinical research involving healthy persons

Moderator  Dirk Lanzerath, European Network of Research Ethics Committees (EUREC)

Speakers  Caroline Ollivier-Yaniv, Université Paris-Est Créteil (France)
Karim Ndiaye, ICM (France)
Marie-Noëlle Ungeheuer, Institut Pasteur (France)

Q&A

► 12H00 – 13H00 • Roundtable 5
Non-drug related clinical studies: vaccines, living cells donation, medical devices

Moderator  Hélène Espérou, Inserm (France)

Speakers  Wali Diouf, Anrs-MIE (Guinea)
Antony Fuhr, Fraunhofer, (Germany)
Thierry Chevalier, Inserm (France)

Q&A

► 13H00 – 14H00 • LUNCH BREAK

► 14H00 – 15H40 • Roundtable 6
Regulations to protect healthy volunteers
Key features and lessons learned

Moderator  Christiane Druml, Austrian Bioethics Commission & Medical University, Vienna (Austria)

Speakers  François Eisinger, Institut Paoli-Calmettes (France), to present the National Registry of Volunteers for Biomedical Research (Data from General Directorate of Health/French Health Ministry)
Henri Caplain, Association Française de Pharmacologie Translationnelle (AFPT) (France)
Chun Keat Chew, Institute for Clinical Research (Malaysia)
Malcolm Boyce, Hammersmith Medicines Research (UK)
Nandini Kumar, FERCI (India)
My Elhassan Elkarimi Anti-Poison & Pharmacovigilance Center (Morocco)

Q&A

► 15H40 – 15H55 • BREAK
15H55 – 17H15 • Towards Good Practices

Aiming for 4Rs: Respect, Reduce, Refine and Replace healthy volunteers

Moderators Paul-Loup Weil-Dubuc & Vincent Israel-Jost, EERIdF, Univ. Paris Saclay, (France)

Speakers Healthy Volunteers as Model Organisms: Borrowing from Animal Research Ethics to Improve Human Trials: Jill A. Fisher University of North Carolina (USA)  
Respect: David B. Resnik, NIEHS (USA)  
Reduce: Pierre Demolis, Agence Nationale de Sécurité du Médicament et des produits de santé (France)/ European Medicines Agency  
Refine and replace: Marylore Chenel, Pharmetheus, (Sweden) 
Perspectives for future guidelines: Lembit Rägo, CIOMS Q&A

17H15 – 17H45 • Keynote Lecture

Introduced by Hervé Chneiweiss, President of the Inserm Ethics Committee

Ezechiel Emanuel 
Vice Provost for Global Initiatives, Co-Director, Healthcare Transformation Institute, University of Pennsylvania (USA)