Instituto de Bioética da Universidade Católica Portuguesa
Health Ethics Committee's Online Webinar - March 17, 2026

The VOLRETHICS Association:

Protecting and Empowering Healthy Volunteers

VOLRETHICS Association's Board: François Bompart, François Hirsch, Lorenzo Montrasio, Luc Bigel, Nadina Stadler, Shadreck Mwale, Yves Donazzolo.

From the VolREthics Initiative

- Founded in 2022 by France's Inserm Ethics Committee
- Informal international network of 200+ people
- Key achievement: 2024 Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials

To the VOLRETHICS Association

Founded in July 2025 to provide a legal framework and enable fundraising

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The VoIREthics initiative

(Volunteers in Research and Ethics)

VOLRETHICS objectives (2022)

- To document the ethical and scientific issues related to healthy volunteers around the world

- To build a repository of new insights and best practices to safeguard the rights, well-being and safety of healthy volunteers globally

VOLRETHICS Association – Advisory Committee

January, 2026

Elisabeth Allen	South Africa		**Sucheta B Kurundkar**	India
Deepa Arora	India		**Dirk Lanzerath**	Germany
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Nandini Kumar	India		**Vania Wisdom**	UK

Affiliations not shown : advisors act in their personal capacity.

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What have we learnt since 2022 ?

Large variety of healthy participants' involvement in research

Interventional studies

- Pharmaceuticals
- Vaccines
- Devices
- Biotherapies
- Environmental exposure
- Controlled Human Infection Challenges

Non interventional studies with or without biological samples collection: control participants, physiology, physiopathology, epidemiology, genetics, nutrition, imaging studies, human and social sciences, behavioural sciences, preventative or diagnostic strategies…

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VOLRETHICS' focus on « healthy volunteers »

We focus on **interventional clinical trials with medicinal products where there is no potential direct health benefit for the individuals involved**, because these studies expose healthy volunteers to the highest risks of

- **Being harmed**
- **Being exploited** through repeat participation to "commercial trials"
- **Having their well-being affected** by strict study conditions.

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Available information on healthy volunteers

Available data

- **Few scientific publications, mostly from the USA**
  - USA: « professional healthy volunteers », « research underclass » (J Fisher, D Resnik, C Eliott, R Abadie and teams)
  - UK: healthy volunteers in commercial drug trials (S Mwale, 2017)
  - Motivations, informed consent: India (Doshi 2013), Brazil (Nappo 2013), Israel (Rabbin 2006), Rumania (Antonesi 2012), Sweden (Rein-Hedin, 2025)
  - Over-volunteering, Japan (Fukase, 2026)

- **Limited publicly available data**
  - Privately-owned data: pharmaceutical firms, Contract Research Organisations
  - Publication of Phase I studies in public databases: not compulsory (USA) or non-publicly available (EU).

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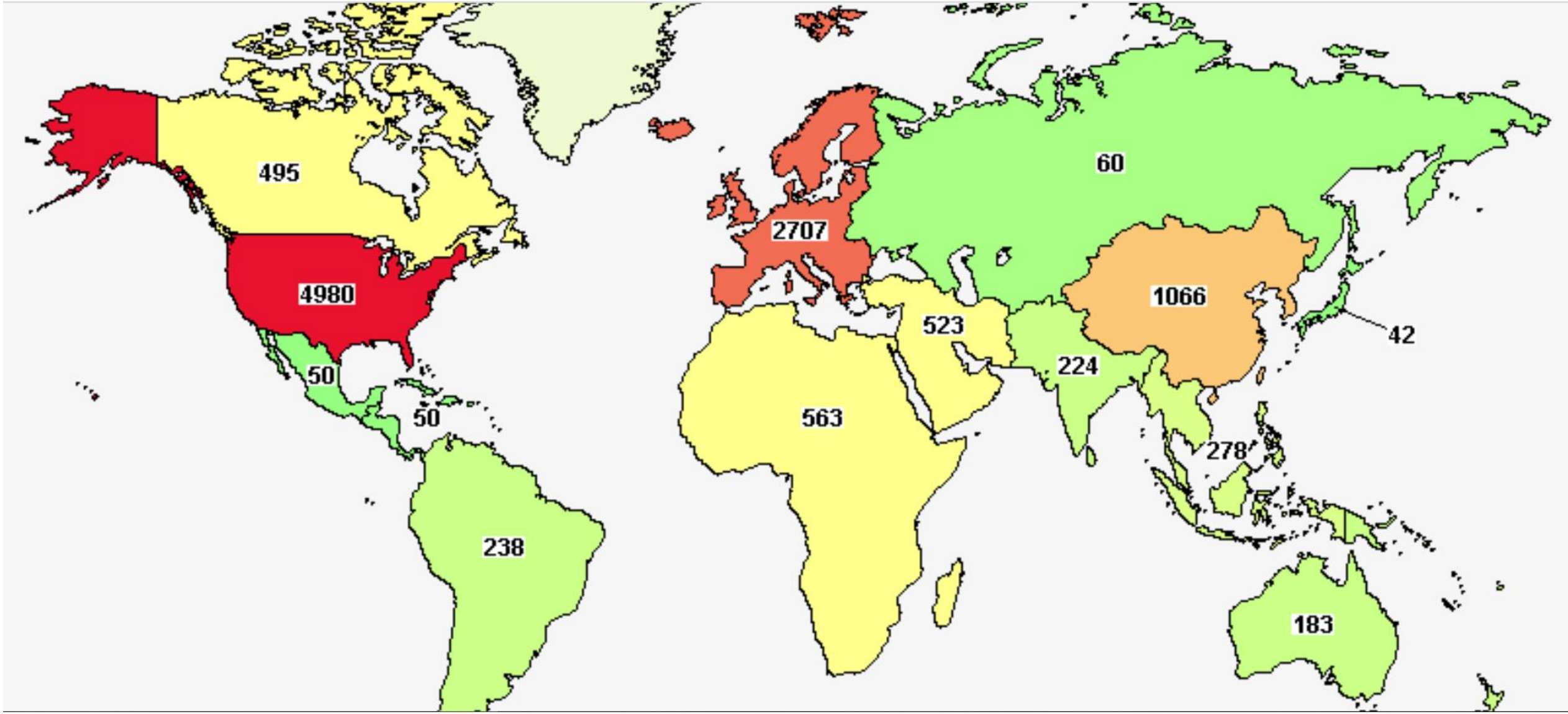
clinicaltrials.gov database

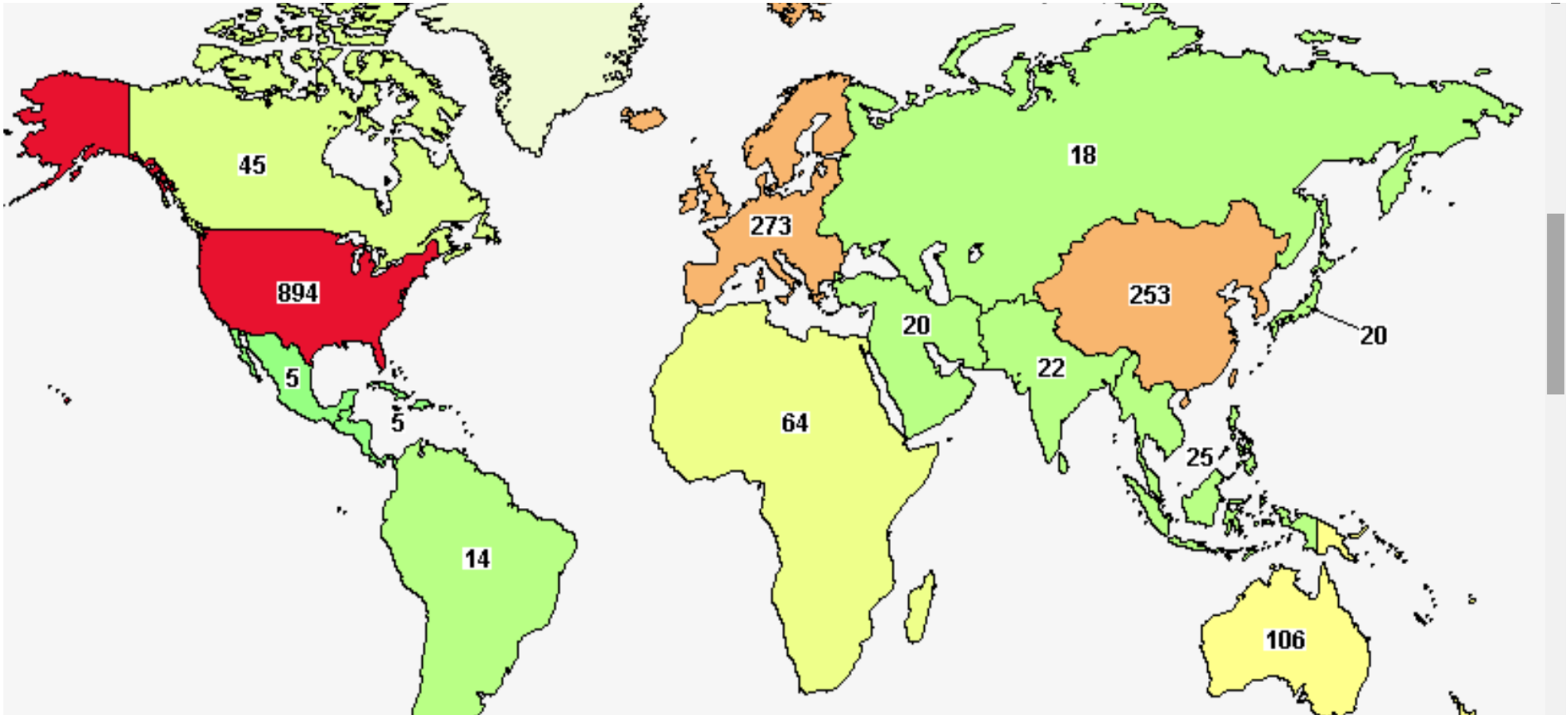
January, 2022

12,858 active interventional studies with healthy volunteers



1,916 active Phase 1 & Early Phase 1 interventional studies

(Non-mandatory registration)



Clinicaltrials.gov database (January 2022)

At least 13,000 interventional studies (drugs, devices, or biologics) involving healthy volunteers ongoing worldwide

Of which approximately 85% are NOT « First-in-Man » Phase I studies but mostly pharmacokinetic studies

Roughly

- 50% in the Americas
- 20% in Europe
- 15% in Asia
- 8% in Africa and Middle-East

Limitations of this work

- Limitations of databases in terms of data accuracy, consistency, completeness, duplication, etc
- Databases not designed to be used for research purposes e.g. to give combined information on numbers of patients, volunteers, etc.

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How are healthy volunteers protected among “research participants” ?

GCP, CIOMS and Declaration of Helsinki

- **Good Clinical Practice**, ICH guidelines reference E6. *"trial participants"*

- **CIOMS - Council for International Organizations of Medical Sciences** International ethical guidelines for health-related research involving humans (2016). *"human beings", "research participants", "human subjects"*

- **Declaration of Helsinki** Revised 2024 version states, for the first time since 1964, that its provisions apply to all "*research participants*" "whether patients or healthy volunteers" (Paragraph 2).

All focus on **patients** involved in research

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Very few countries have specific laws and regulations for healthy volunteers

National registries to ensure respect of wash-out periods between trials:

1. **France 1988,** Volontaires Recherche Médicale (VRB)
2. **UK 2013,** The Over-volunteering Prevention System (TOPS)
3. **Malaysia 2021,** National Healthy Volunteer Research Registry (NHVRR)
4. **Morocco** work in progress

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Why does this matter ?

Healthy volunteers vs. Patients in research

- They are healthy : no expectation of direct health benefit, different benefit/risk balance from patients

- They receive financial compensation : risk being exploited when in situations of vulnerability

- Studies are run under very constrained conditions that may impinge on their well-being

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A « research underclass* »

US and UK empirical studies have shown that healthy volunteers are motivated to enroll in clinical trials because of the payments they receive in exchange for their participation

- Abadie R. The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects. Durham, NC: Duke University Press; 2010.
- Fisher JA. Adverse Events: Race, Inequality, and the Testing of New Pharmaceuticals. New York: New York University Press; 2020.
- Mwale S. Healthy volunteers in commercial clinical drug trials: when human beings become guinea pigs. London: Palgrave MacMillan, 2017.

In the US, ethical concerns about exploitation are exacerbated by social inequalities that have led to the overrepresentation of Black and Latino healthy volunteers in paid clinical trials.

Fisher JA, Kalbaugh CA. Challenging assumptions about minority participation in U.S. clinical research. Am J Public Health 2011;101 (12):2217–22.

*Elliott, Carl, and Roberto Abadie. 2008. "Exploiting a research underclass in phase 1 clinical trials." New England Journal of Medicine 358 (22):2316–2317.

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Excerpts from VOLRETHICS regional meetings

India

- 1-week bioequivalence study = 10 times what a daily wage earner would have otherwise earned
- "Blood Money" WhatsApp group: a 32 years old volunteer took part in over 40 studies: *"It isn't uncommon for volunteers to break trial rules and lie"*

North America

- "Need to Pay the bills", clinical studies as "gig jobs"
- Very experienced healthy volunteers, some with over 20 studies, know "how to behave" to be recruited and retained
- Payments used to retain volunteers in studies: conceal adverse events, feel punished if unable to complete study

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Why is so little attention paid to healthy volunteers?

Why is so little attention paid to healthy volunteers ?

Unlike patients, healthy volunteers are not organized to get their voices heard

Very rare severe accidents Northwick Park (UK) 2006 : 6 volunteers developed severe multi-organ failures. Biotrial (France) 2016: 1 death, 5 irreversible brain damages and mental handicaps.

Very limited data on the realities of healthy volunteers' involvement in research

Current system meets the needs of most stakeholders

- Healthy volunteers: payments
- Contract Research Organisations: profitable business
- Pharmaceutical companies: data needed for science and for registration of pharmaceuticals
- Regulatory agencies: data needed for registration of pharmaceuticals

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Why does this matter?

- **Many healthy volunteers belong to economically disadvantaged groups**

- **Ethical issues related with risks of**
  - **Harm**
  - **Exploitation** when in situations of vulnerability
  - **Having their well-being affected**

- **Between-countries differences** (risk of over participation, insurance, etc.)

- **Reputational risks for all stakeholders**

We need an even global playing field for studies involving healthy volunteers

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The Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials

June, 2024

Healthy volunteers' 15 rights in clinical trials

Heathy Volunteers are ENTITLED to:

- 1. Laws and regulations that specifically protect them as research participants,
- 2. Assurance that their participation in research is ethical and scientifically necessary,
- 3. Adequate representation throughout the research process,
- 4. Transparency about clinical trials in which they are involved,
- 5. Adequate research ethics oversight,
- 6. Adequate trial site and investigator oversight,

PROTECTION FROM HARM

- 7. Protection from physical harm,
- 8. Adequate attention paid to their well-being,
- 9. Adequate protection from potential long-term harm,
- 10. Protection from the risks of over-volunteering,

PROTECTION FROM EXPLOITATION

- 11. Recruitment through fair and respectful practices,
- 12. Relevant study information to provide genuine informed consent,
- 13. Fair financial compensation for their participation,
- 14. Post-trial compensation for research-related injury,
- 15. Adequate processes for confidential reporting of concerns.

The Charter is a tool to be used for

- Advocacy on healthy volunteers' specific ethical and scientific issues

- Debates within countries/regions on most adapted ways to protect healthy research participants

The Charter is available in 10 languages

- Arabic
- English
- Chinese
- French
- German
- Hindi
- Italian
- Malay
- Portuguese
- Spanish

Human Research Ethics Committees

The Global Ethics Charter

Human Research Ethics Committees

Research Ethics Committees must protect healthy volunteers in situations of vulnerability from risks of

- **Being harmed.** Administering a pharmaceutical compound, even a well-known one, to a healthy person always carries some level of risk
- **Being exploited** when in situations of vulnerability
- Having their **well-being affected.**

Ethics Charter : Article 5.

Adequate research ethics oversight.

•Scientific and ethics review boards involved in assessing healthy volunteer trials should possess the necessary expertise, training, and resources to thoroughly assess & integrity of such trials.

•Board members should understand the risks specific to healthy volunteer trials and how to minimise them.

•Members should include at least one representative of healthy volunteers' interests who has the requisite knowledge and experience to protect them from harm

Ethics Charter : Article 12.

Relevant study information to provide genuine informed consent.

In addition to following all current guidelines and ethical standards, informed consent materials and processes should be tailored to address the specificities of healthy volunteer trials.

Information about financial compensation should include details about when and how payment will be made, how compensation will be determined if the study is stopped early or the participant exercises their right to withdraw from the research, and any potential economic risks to participants (e.g., income tax consequences or eligibility for social services). Additionally, detailed information about the risks of failing to follow protocol restrictions, such as dietary requirements and rules about frequency of study enrolment, should be provided.

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Ethics Charter : Article 10.

Protection from the risks of over-volunteering

Preventing over-volunteering, i.e. not respecting exclusion (or “washout”) periods between trials, is crucial to protect participants and the integrity of clinical trials.

Countries should develop and maintain mandatory systems across all clinical research settings to prevent over-volunteering.

Consistent with national and international data privacy requirements, these systems should enable individual participant identification to ensure healthy volunteers adhere to the exclusion periods between trials. Wherever possible, these systems should operate across national borders.

Ethics Charter : Article 15.

Adequate processes for confidential reporting of concerns.

Procedures should be established to allow healthy volunteers to report any concerns to clinical site staff, ethics review boards, or regulatory agencies during and after the clinical trial, without fear of reprisal or loss of entitled financial compensation.

Details on how and where volunteers can report concerns should be clearly outlined in informed consent documents. The volunteers' identity should be confidential unless their identity is essential for resolving the complaint and should only be shared with their permission. Participants should be informed about the outcome of any complaints. Written records should be maintained that document reported issues and the corresponding actions taken.

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VOLRETHICS Association : Vision

A global association with a base in Europe (French “Loi de 1901”)

That supports a network of regional / country associations (e.g. India, North America, Latin America, Africa…).

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VOLRETHICS Association : Mission

- **To promote global awareness of, and debates over, the specific ethical and scientific issues** related to the involvement of healthy volunteers in research

- **To foster the development of good practices, guidelines, regulations and laws**

- **To support research** to better characterize ethical, societal and scientific issues that are specific to the involvement of healthy volunteers in research

- **To foster the creation of support groups of healthy volunteers**

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Some VOLRETHICS Impacts

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Scientific Publications (I)

https://volrethics.org/index.php/publications/

nature medicine

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nature › nature medicine › correspondence › article

Correspondence | Published: 14 August 2023

The VolREthics initiative to protect the well-being of healthy volunteers in biomedical research

François Bompart, Jill A. Fisher, Elizabeth Allen, Esperança Sevene, Nandini Kumar, Chun Keat Chew, Valeria Fink, Dirk Lanzerath & François Hirsch

Nature Medicine **29**, 2393–2394 (2023) | Cite this article

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A global ethics charter to protect healthy volunteers

Jill A Fisher • François Bompart • Lorenzo Montrasio • Shadreck Mwale • Chun Keat Chew • Sucheta B Kurundkar • Yves Donazzolo • François Hirsch • Show less

Published: August 17, 2024 • DOI: https://doi.org/10.1016/S0140-6736(24)01480-6

COMMENTARY

THE AMERICAN JOURNAL of MEDICINE®

Implementing a Global Ethics Charter to Protect US Healthy Volunteers

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Global effort aims to protect health and safety of human 'guinea pigs' in drug trials

Healthy volunteers—who usually join studies for money—deserve special attention, researchers say

8 MAY 2024 • 8:50 PM ET • BY MARTIN ENSERINK

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Scientific Publications (II)

THE EUROPEAN SOCIETY OF MEDICINE
Medical Research Archives, Volume 14 Issue 2

RESEARCH ARTICLE

Over-volunteering in Phase I clinical trials: data from a healthy volunteers' registry in Japan

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ABSTRACT

Background. Over-volunteering refers to situations where healthy human volunteers (HVs) participating to clinical trials do not respect exclusion periods between trials, usually to maximize financial gains. By doing so, HVs expose themselves to potential safety risks and may compromize the trials' data integrity. The extent of this phenomenon is poorly documented in the scientific litterature.

THE LANCET

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Declaration of Helsinki's missed opportunity for healthy volunteer trials

François Bompart [a] ✉ · Jill A Fisher [b] · Sucheta Banerjee Kurundkar [c] · François Hirsch [a] · Shadreck Mwale [d]

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Several International Recognitions

Aug. 2025: **DNDi Foundation** endorses the Ethical Charter

Sept. 2025 : the **European Commission** includes VOLRETHICS among the initiatives "*that participate in Horizon Europe projects aimed at promoting ethics and integrity in research*", to ensure the proper ethical dimension of EU-funded projects

Oct. 2025: **Inserm** endorses the Ethical Charter

Malaysian National Pharmaceutical Regulatory Agency, Ethical Charter's endorsement in discussion

Preparation of guidance document for **Irish RECs** to better evaluate research with HV

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Why join the VOLRETHICS Association ?

- Join a global network committed to the ethical conduct of biomedical research with healthy volunteers, started in 2022.
- Shape international standards to harmonize ethical frameworks across regions.
- Participate to projects funded through the Association.
- Get support for your own projects.

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Yearly fees structure

Legal entities Public and private institutions, companies and agencies	**Individuals** Based on Gross Annual Income	**Healthy volunteers**
500 € (Euros)	Less than 10,000 € : **10 €** From 10,000 to 20,000 € : **20 €** Above 20,000 € : **50 €**	Token contribution: ≥ **1€**

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For more Information

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