



Opinion by letter No 17 on the appropriateness of indicating ethnicity in protocols of clinical trials on healthy volunteers

*Request for opinion dated 8 April 2024 from the Medical Ethics
Committee of Iris Hospitals South*

*Admissibility of the request and adoption of the opinion by letter:
Committee plenary session of 10 June 2024*

Preliminary Warning:

The committee's opinions are drafted in Dutch and French. Please consider these two language versions as official, even if translations in other languages are available.

9 September 2024

Dr. G. Callebaut, Chairman
Dr. G. Bauherz, Vice-Chairman
Medical Ethics Committee
HIS - IZZ

Via email :
comite.ethique@his-izz.be

Contact	phone	e-mail
Sophie Bertrand, Coordinator	02 524 91 84	sophie.bertrand@health.fgov.be
Our reference G:\CSS\BIOETHIC\BUREAU\Vragen-advies\2024 adviesvragen-demande d'avis\12		
Your reference Votre courrier du 8 avril 2024		

Your request for an opinion concerning the appropriateness of indicating race/ethnicity in protocols of clinical trials on healthy volunteers

Mr Chairman,
Mr Vice-Chairman,

In a letter dated 8 April 2024, you submitted the following request to us from the Medical Ethics Committee of Iris Hospitals South (IZZ):

"On 15 March 2007, the Medical Ethics Committee of Iris Hospitals South asked the Advisory Committee on Bioethics for an opinion on the appropriateness of indicating race/ethnicity in clinical trial protocols involving healthy volunteers.

Your Committee replied by letter dated 23 June 2009 (ref. G/Bioethic/Presvz2009/090706), informing us that no formal opinion had yet been issued, but that "The Advisory Committee, which has not yet been constituted, will reconsider the draft opinion you have submitted to us", and that "we will be sure to inform you as soon as the opinion is definitive". We have not heard from you since then.

We would therefore like to remind you of the reasons for our request for an opinion.

Most randomised prospective studies submitted to us ask about the "ethnicity" of the participants. The categories used are almost always as follows: "Caucasian, black, Asian, Hispanic, other".

We almost always oppose this indication. We believe that this feeling is shared by most Belgian ethics officers, but these concerns are rarely acted upon. It is likely

that the importance of this question is considered secondary to the importance of the study.

We would like to hear the opinion of the Belgian Advisory Committee on Bioethics on this matter.

Attached: an article on this topic published by Dr Bauherz in the 11212023 issue (December 2023) of the journal Ethica Clinica. [free translation]"

The Committee wishes to respond to the request for an opinion by means of this opinion by letter.

* * *

Justifying the collection of data on the ethnicity of healthy volunteers in phase 1 studies

Diversity, equal rights and inclusion are important principles in our society. This is precisely why, from time to time, ethics committees ask questions about the collection of data on the ethnicity of healthy volunteers in phase 1 studies.

Ethnicity is known to play a role in responses to medication¹. This has not so much to do with ethnicity itself, but mostly with genetic background. Until pharmacogenetics reaches a sufficient level of maturity, the ethnic background of the participant provides complementary information. Other dietary habits or lifestyles related to ethnicity may also play a role. While the genetic background may be the same, eating habits and lifestyles are often a matter of cultural choice. People of a certain ethnicity may have lived in another environment for a long time and adopted the customs of that environment. That means that ethnicity does not necessarily determine lifestyle.

Recent FDA "draft guidance" strongly encourages the collection of data on ethnicity (update of 2016 guidance) and is publicly available for comment². This document also refers to the mandatory diversity of participants in clinical trials. After all, once commercialised, the drugs studied will be applied in a diverse population. It is essential to know about the different effects, including side effects, in order to provide the best possible care for a diverse group of people rather than sticking to a "standard" model that has long been dominant.

It should be added here that the ethnicity of participants reported in this way is self-reported.

¹ Olafuyi, O., Parekh Inter-ethnic differences in pharmacokinetics - is there more that unites than divides?, N., Wright, J. & Koenig, J. Inter-ethnic differences in pharmacokinetics - is there more that unites than divides? Pharmacol. Res. Perspect. 9, e00890 (2021).

² <https://www.raps.org/News-and-Articles/News-Articles/2024/1/FDA-proposes-standards-for-collecting-and-reporting>

The following are examples of self-reported ethnicity (in alphabetical order):

- African: This includes many different ethnic groups on the continent, such as Yoruba, Igbo, Zulu and many others.
- Asian: This includes groups such as Chinese, Japanese, Korean, Indian, Vietnamese and many others.
- European: This includes groups such as German, French, Italian, Spanish, Polish and many others.
- Hispanic or Latino: This refers to people who originate from Spanish-speaking countries, including Mexico, Central America, South America and the Caribbean.
- Native American: This refers to the indigenous peoples of the Americas, including groups such as Cherokee, Navajo, Sioux and many others.
- Inuit is a specific group with a shared cultural, linguistic and historical background living mainly in the Arctic regions of Alaska, Canada and Greenland. Although sometimes included under the broader term "Native Americans", Inuit have a unique identity and culture that sets them apart from other indigenous groups in North America.
- Middle Eastern: This includes groups such as Arabic, Persian, Turkish, Kurdish and many others.
- Pacific islander: This includes groups such as Polynesian, Melanesian and Micronesian peoples.

It is important to remember that ethnicity is complex and can be self-identified. People may identify with multiple ethnicities or have mixed origins. There are also numerous subgroups and different cultural identities within each broad category. In addition, some classification systems also include:

- Mixed or Multiple Ethnic Groups: This recognises individuals who identify with more than one ethnicity.
- Other: This category allows the inclusion of individuals who do not identify with any of the ethnicities listed.

The term "Caucasian" has become outdated and problematic. It was once a broad racial classification used to describe people of European origin but has no basis in modern scientific understanding.

Here are some more important aspects to consider:

Ethical aspects

- **Informed consent:** volunteers should be fully informed about the purpose of data collection in relation to ethnicity and how their data will be used. This requires a transparent

and understandable consent procedure. Communicating ethnicity can be extremely sensitive for some volunteers. This information falls into the category of sensitive data under the GDPR, which implies precautions at every level (see below, privacy and confidentiality). It is therefore important to clearly indicate the justification for collecting these data and limit further data processing to this end. In addition, the "other" category offers participants the possibility of not acknowledging any of the ethnicities listed.

- **Non-discrimination:** neither recruitment nor participation in scientific research should involve discrimination based on ethnicity. Data analysis and interpretation should focus on identifying effects on health and not on confirming biases or stereotypes.

- **Privacy and confidentiality:** the privacy of volunteers and the confidentiality of their data must be ensured at all times. Ethnic data should be stored and shared securely, and be accessible to authorised researchers only. Publications will never reproduce individual ethnic data. As soon as researchers are able to anonymise the data without harming the scientific integrity of the research, this should be done.

Scientific aspects

- **Scientific relevance:** collection of data on ethnicity is justifiable on the basis of the scientific robustness of clinical trials and should make an effective contribution to the health of all population groups.

- **Data analysis and interpretation:** the analysis and interpretation of data on ethnicity must be based on reliable methods. Account must be taken of the complexity of ethnic diversity and the potential impact of other confounders on the data collected, such as lifestyle and other psychosocial factors.

- **Transparency and publication:** the methodology, findings and implications of collecting data on ethnicity should be transparently reported in scientific publications. This contributes to public scrutiny and discussion of the study.

In addition to these ethical and scientific aspects, it is important to consider the local context and regulations regarding data collection and research with trial subjects.

It is essential that the benefits and risks of collecting data on ethnicity in phase 1 studies are carefully weighed. Open dialogue and collaboration between researchers, ethicists and medical ethics committees, policymakers and the public are crucial for developing responsible and ethical practices in biomedical research.

Yours sincerely,

(signed)

Jan De Lepeleire,
Chairman of the Advisory Council on Bioethics

This opinion by letter was prepared by Patrick Cras, Vice-Chairman.