

The following declarations, directives and guidelines summarize the ethical principles on conducting research in human subjects. Note that these do not only apply to any procedures in humans which are invasive or taking biological specimens (like taking blood, urine, cerebrospinal fluid, DNA, or tissue biopsies) but also to all non-invasive procedures (be it even measuring blood pressure or performing an ECG). They apply to any research in human subjects conducted by practitioners, academic institutions, or the industry.

Ethical principles of research in humans are laid down in detail in the “Declaration of Helsinki”¹ by the World Medical Association. The standards of ethical business practices for Thermo Fisher should also be viewed against the Guidance and Directives Documents of the European Union and the US Food and Drug Administration (FDA)² pertaining to research in human subjects. Note that also most other countries outside the US and EU have their own national guidance documents and legislation, but US and EU set the standards.

Of course, Thermo Fisher may argue that they are only selling the kits for DNA sampling, and that these are intended for forensic use. We can respond that

- DNA sample collection in Tibet (and elsewhere in China) violates ethical standards that we are adhering to in our world in that a very global purpose of “preventing crime” and “finding lost persons” in the absence of a concrete cause is not sufficient to justify widespread collection of samples.
- It cannot be excluded that the stored samples may also be used for other purposes such as research. Does Thermo Fisher have any clause in their purchase agreements to prevent this use?

We should reject the very narrow purpose of “forensic” use that Thermo Fisher may claim and remind them that in Tibet procedures are performed in human subjects by taking biological specimens, and that these are further processed, analyzed, and stored. These specimens contain the probably most individual and sensitive information about a subject, i.e., their individual genetic outfit. Even more, these procedures are also performed in a group of most vulnerable subjects, i.e., children. Therefore, Thermo Fisher in our opinion must adhere to ethical standards that apply to human research.

Thermo Fisher are explicitly mentioning adherence to the Declaration of Helsinki and “privacy and data protection standards” in their “bioethics guiding principles”. Of note, they have a “Bioethics Committee” in place to ensure adherence to “ethical business practices and standards”³.

Here is an excerpt of the most relevant points of the Declaration of Helsinki and the US and EU guidelines to adhere to in the context of DNA sampling. The stipulated ethical standards apply not only to patients, but to all populations: healthy adults, children, incompetent or incapacitated persons, and dependent subjects such as prisoners. The referenced documents go further to other topics that do not apply to our campaign. Points of relevance to us are the following obligations before any procedure is performed in a subject:

¹ <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

² <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF>

https://ec.europa.eu/research/participants/data/ref/fp7/89807/informed-consent_en.pdf
<https://www.fda.gov/patients/clinical-trials-what-patients-need-know/informed-consent-clinical-trials>

³ <https://corporate.thermofisher.com/content/tfcorpsite/us/en/index/corporate-social-responsibility/operations/governance-and-ethics.html>

- An explanation of the purposes of the procedures must be provided, in particular if these involve genetic tests, and that participation in the procedures is voluntary.
- The explanation must be administered in a language that is understandable to the subject, is not coercive, not exculpatory (e.g., to coerce subjects to waive their legal rights), and not exaggerate benefit versus risks or inconveniences.
- Assent by children must be obtained, apart from parents' or legal representatives' consent, as and when the children reach the adequate age for giving assent, and information must be provided in understandable language or other forms such as pictorial descriptions. Assent is defined as an "affirmative agreement to take part . . . , not just the failure to object".
- A statement must be provided describing the procedures adopted for ensuring data protection, confidentiality, privacy including duration of storage of personal data.
- A statement must be provided offering the subject the opportunity to ask questions and to withdraw consent at any time without consequences.
- Consent must be given in writing and be adequately documented and archived.

On top, Thermo Fisher should be reminded and asked whether they control their customers or intermediate partners whether they adhere to Thermo Fisher's own ethical standards.

The involvement of Thermo Fisher seems to go beyond just selling kits. In the article from The Intercept⁴ you can see that Thermo Fisher sold and upgraded a sequencer and other equipment.

Here is an excerpt from the report:

"The deployment of DNA databases across the whole of China lacks elementary fundamental rights safeguards," said Yves Moreau, a bioinformatician at Belgium's University of Leuven who uncovered the procurement documents through the Chinese search engine Baidu. "Western suppliers should not aid and abet those abuses."

In October 2021, a [second tender announcement](#) shows, police in Lhasa spent \$173,000 upgrading a "3500 sequencer," a product name and price range matching Thermo Fisher's 3500 Genetic Analyzer line. Other documents hosted on a third-party government tender site suggest that Tibetan police also [bought Thermo Fisher equipment](#) in August of last year.

⁴ <https://theintercept.com/2022/09/13/china-tibet-police-dna-thermo-fisher/>