Directive on Research Projects Involving Blood Sampling in Humans

LEX 1.5.10

31st March 2014, status as at 15th March 2021

The Direction of the Ecole polytechnique fédérale de Lausanne hereby adopts the following:

Preamble

Any research involving humans for the purposes of research on humans requires approval from the Cantonal Ethics Committee on Human Research (*Commission cantonale d'éthique de la recherche sur l'être humain CER-VD or CCER*[1]). Such approval serves to guarantee protection of research subjects and to ensure the quality of results.

This Directive defines, on the one hand, the procedure to be followed on the EPFL campus in taking blood from volunteer donors and, on the other hand, the responsibilities and obligations of the various participants.

The blood collected shall be used exclusively for basic research projects.

Article 1 Responsibilities

[1] Application for authorisation from the Cantonal Ethics Committee and the proper conduct of the project are the responsibility of the project manager. The relevant information on how to file an application can be found on the website mentioned in the preamble, i.e. CER or CCER

[2] The Department of Security, Safety and Facilities Operations (DES) ensures compliance and the quality of blood samples by providing an approved medical facility through the EPFL Health Point, a collaboration between EPFL and Unisanté. It includes a doctor, an EPFL medical assistant and three nurses from Unisanté.

[3] The EPFL Health Point guarantees the individual's freedom of choice, protection of personal data, the professional quality of blood collection, and sample coding and follow-up where applicable.

Article 2 Blood collection

[1] This Directive governs blood collected on campus from volunteer donors for research purposes.

[2] The blood required from third-party institutions (e.g. Red Cross) requires an agreement between the project manager and the institution prior to approaching the Cantonal Ethics Committee.

[3] The blood is collected in accordance with the specific requirements of the project and in compliance with the Cantonal Ethics Committee's authorisation. The volume of blood taken depends on the doctor's decision and specifications given in the project submitted to the Cantonal Ethics Committee.

[4] Blood samples shall not be tested to detect any infectious agents.

[5] For safety reasons, employees shall not use their own blood for experimental purposes.

[1] EPFL Lausanne, Smart Living Lab Fribourg, EPFL Valais Wallis, Microcity Neuchatel: "Commission cantonale d'éthique de la recherche sur l'être humain (CER-VD)" ; Campus Biotech Geneva: "Commission cantonale d'éthique de la recherche (CCER)"

Article 3 Sample coding

[1] Data management related to blood samples collected on campus is performed by the EPFL Health Point. As only coded samples may be handed to the researchers, these samples are coded upon blood collection. The code should allow the Health Point to ensure sample traceability if necessary. Samples from third party institutions shall likewise be coded before being handed over to researchers.

[2] Should the researchers find, during an experiment, that a sample is abnormal, they are required to inform the EPFL Health Point doctor, who will decide on the next steps.

Article 4 Internal procedure for the use of human blood

[1] Any group wishing to work with human blood shall observe the following rules:

1. apply for authorisation from the Cantonal Ethics Committee; the process is available on the Cantonal Ethics Committee's website;
2. follow the simplified procedure approved by the Cantonal Ethics Committee;
3. send a copy of the authorisation and of the Consent Form, as well as the inclusion and exclusion criteria, to the EPFL Health Point (sante@epfl.ch);
4. inform volunteer donors of the purpose and procedure of the research project;
5. have the voluntary donors sign the "Consent Form" to be handed to the EPFL Health Point when giving blood, which should be countersigned by the person in charge of taking the sample;
6. contact the EPFL Health Point to organise blood collection by the doctor, or by a registered nurse or medical assistant to whom this task has been delegated. The doctor checks that the principle of free and voluntary donation is observed and that the inclusion and exclusion criteria are met by the blood donor;
7. restrict the number of samples to that required for the experiment;
8. the Health Point doctor keeps a file on each project, including data on donors, under lock and key;
9. inform the EPFL Health Point doctor when the project is completed. The occupational health doctor shall keep all data for 10 years from the last blood collection, after which the data is destroyed.

[2] N.B.:

1. all cultures generated from human blood samples are considered Risk Group 2 and shall be handled in Biosafety Level 2 (P2 or BSL2) laboratories;
2. waste shall be inactivated by autoclaving or by NaOH treatment before disposal.

Article 5 Entry into force

The present directive entered into force on 31st March 2014. Status as at 15th March 2021 (version 1.3).

On behalf of the EPFL Direction:

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