Guidelines for storage of body materials in beta medical research

General:

The General Data Protection Regulation (GDPR) is the legislative framework for the storage and destruction of bodily materials.[1]

Collection of body materials:

The collected material is pseudonymised and coded by the researcher immediately after collection, before it is stored and analyzed. This can be traced back to the individual test subject via a (encrypted) key file.

Storage and destruction of body materials[2]:

All body materials collected are stored coded during the examination in a specially equipped storage area (e.g. a freezer)[3]. Registration of all incoming body materials is done by the researcher under the responsibility of the principal investigator. The freezer coordinator has a controlling role in this. The body materials must be destroyed immediately after the analysis or no later than one month after acceptance of the intended publications. No leftover materials[4] are kept longer than strictly necessary.

Collected body materials that must be kept until the moment of acceptance of the intended publications and that return to the FSW after external analysis, are stored in a storage facility designed for this purpose. The principal investigator supervises the destruction of the body materials after publication. The freezer coordinator has a controlling role in this.

The method of storage and destruction of the collected body materials and any exceptions to storage periods must be included in the data management plan.

Transport of body materials:

The researcher is responsible for transporting the body materials to the external lab. It is not allowed to transport a bulk of samples in the train (exception are samples that must be transported after testing subjects).

Body materials must be properly packaged and presented to the carrier in a coded form. The packaging must clearly state that it contains human materials.

The preferred supplier for transport is *Biologistic*. Clear agreements have been made with this transport company and a processor agreement is available that has been approved by the FSW information manager. If there is a valid reason to choose a different transporter, a processing agreement must be concluded in advance. This must be coordinated with the FSW information manager.

---

[1] The future Body Material Control Act (Wzl) contains a general framework for the purchase, storage, provision, use and destruction of human material for purposes other than current diagnostics or medical treatment of the donor and may eventually become the additional or replacement legislative framework.

[2] The FSW Beta Medical Facilities Handbook describes the protocols for taking saliva and blood, among other things.

[3] Described in the FSW Beta Medical Facilities manual (rules of use for freezers and freezer space).

[4] Small amount of the collected human tissue that remains after examination / analysis.

Deviation from these guidelines:

If under certain circumstances it is necessary to deviate from these guidelines, coordination must be sought with the FSW information manager, freezer coordinator, CEP and / or CME / CCMO and this must be included and substantiated in the data management plan.