Guidelines for storage of sperm/semen.

1. The objective of the sperm biobank

A sperm biobank has been established at the Unit for Assisted Reproduction at the Women's Clinic, Haukeland University Hospital, where semen/sperm can be stored in frozen form. This is a diagnostic and treatment biobank. The stored material may be used for future assisted reproduction treatment for the spouse or co-habiting partner of men who must undergo medical treatment that may affect fertility or who, for various medical reasons, have a non-existent or substantially impaired ability to produce fresh semen samples of sufficient quality.

"The purpose of this Act is to ensure that the collection, storage, processing and destruction of material that forms part of a biobank are carried out in an ethically sound manner, and that biobanks are used for the benefit of individual people and of society as a whole. These activities shall take place in accordance with fundamental respect for the right to privacy and the principles of respect for human dignity, human rights and personal integrity, and without any discrimination of individuals from whom the biological material originates." (Excerpt from the Norwegian Act relating to Biobanks).

2. Responsibility and control

Haukeland University Hospital is responsible for the operation of the sperm biobank. Secure routines have been established for the collection, processing, storage, collection and transport, as well as for the destruction, of stored semen/sperm.

In exceptional circumstances, technical problems may result in donated samples becoming lost or destroyed whilst in storage.

3. Scope

The sperm biobank can freeze and store semen/sperm from selected patients. The offer is available to patients suffering from a disease, or who are to be subject to treatment that may reduce or completely impair their fertility, and to patients whose ability to deliver fresh semen samples of sufficient quality is non-existent or significantly impaired. Samples will be derived from ejaculate or from testicular tissue. In order for sample material to be frozen, sperm **must** be present in the sample material.

4. Consent/legal basis for storage of sperm

Collection, storage and treatment of patient semen/sperm requires the donor's consent. This also applies to use of the material for quality control and method development purposes. In the event of changed, expanded or renewed use of the material, a new, voluntary, explicit and informed consent must be obtained. The patient shall be given the consent counterpart. Consent may be withdrawn at any time.

The Section is obligated to keep a donor register including health data relating to donors, donated cells and tissue and the recipients of these (donation register). The donation register shall ensure full traceability in connection with treatment. The traceability requirement shall at all times take precedence over the donor's wish to remove information pertaining to themselves once the relevant material has been used. Each year, the Section prepares a report for the Norwegian Directorate of Health wherein all data accessible to third parties has been anonymised or encoded. The patient must consent to the health data being processed in the donation register.

The normal storage term is 20 years.

Samples will be destroyed

- once the storage term expires, unless an application for extension is available
- on receipt of a written request for destruction of semen sample/withdrawal of consent.
- after the patient's death, unless the decease`s surviving spouse/ co-habiting partner wishes to use the sample for fertility treatment and can document that this is in line with the wishes of the deceased.
  (The Biotecnology Act §2-17)

At the time of sample submission, HIV 1 and 2, Hepatitis B (HBs antibodies, HBs antigens and HBc antibodies Ig2) and Hepatitis C tests shall have been performed and confirmed. The material will be quarantined until its viral infection status has been established.

The purpose of the sperm biobank is for the material stored therein to be used for assisted reproduction treatment. The operations are thus regulated by the Biotechnology Act. The Act relating to Biobanks complements these regulations.

The sperm biobank may not conduct research or experiments in connection with the destruction of the material without the consent of the patient.

5. Storage requirements

The biobank material shall be stored responsibly and in accordance with regulations contained in laws, or pursuant to legislation. The storage activities should be conducted with respect for the donor.

6. Legal basis for use of materials

Stored semen/sperm may only be used to treat the man's spouse or co-habiting partner with whom he lives under marriage-like circumstances. The use of stored semen/sperm requires the written consent of the patient for each individual treatment cycle.

The treating physician at the facility administering the assisted reproduction treatment decides whether or not a couple should be offered treatment. This is done in accordance with the guidelines stipulated in the Biotechnology Act and in consultation with the requisite specialist expertise. The offer to store semen/sperm does not automatically entail entitlement to assisted reproduction treatment.

7. Routines in the event of biobank closure/cessation of operations

In the event of closure of the biobank, notification shall be sent to the Ministry of Health.
The contents may be transferred to another biobank or be wholly or partially destroyed.

8. Information

The patient and, if applicable, their spouse/partner shall be informed of the guidelines at the time of donation and must confirm, in writing, that they have received this information. The patient and, if applicable, their spouse/partner shall also be informed of the chances of achieving pregnancy using stored sperm, any injury risks and other circumstances that may be of interest to them .

9. Consent

NAME:

DATE OF BIRTH:

I hereby accept the terms and conditions outlined in these guidelines:

Location: Date: Signature:

Cross-references

12.3.10.1.1.2-68	Informasjon og samtykke ved tilbod om nedfrysing og lagring av spermiar/sæd

External references

The Act relating to Biobanks, the Biotechnology Act