“The Legal Framework for Biobanks: Belgium”

Pr Myriam Remmelink

Director, Biobank Council, Erasme-ULB

Background

- European Directive **2004/23/CE from European parliament and European Council, du March 31, 2004**
- Belgian Law 19 December 2008, modified in 2013

  (Loi relative à l'obtention et à l'utilisation de matériel corporel humain destiné à des applications médicales humaines ou à des fins de recherche scientifique)
- Pending Royal Decree
- Council of Europe:

  DH-BIO/INF (2014) 3 - Working document on research on biological materials of human origin
  This is no law (yet).

Definitions (Belgian law)

- Human Corporal Material (HCM) :
  - Any biological material from human origin, including human cells and tissues, gametes, embryos, fœtusses, as well as all derivatives disregarding the degree of transformation
- Biobank :
  - The structure that collects, processes, stores and supplies HCM reserved to scientific research, as well as associated data (relative to donor and HCM). This excludes human medical applications which is subject to other specifications..

Applies to: donation, removal, receiving, control, processing, storage, distribution, usage of HCM for scientific research of human application

Generalities

- No publicity (no advertisement)
  - exception : campaign for allogenic « donation » in the context of Public health
- No money
  - No financial compensation allowed for the donor, with the exception of compensation for lost revenue due to the donation.

Role of the Ethical Committees

- Biobank creation

- HCM Usage
  - The research objective must have been validated by an Ethical Committee:
    positive advice necessary

Consent I

- Donor must be adult
- Consent must be given freely, willingly and after having been fully informed
- Donor must be informed in a systematic way for each purpose for which the MCH is kept and must give his consent prior to its use.
- Consent must be written and specify its scope and validity

Consent II

- The consent may be withdrawn at any moment prior to the first processing after HCM collection
- If analysis performed on traceable HCM reveals information pertinent to health of the donor, (s)he must has right to this information

Exception

- Secondary use of HCM
  - Is: any use of MCH that differs the one to which the donor has explicitly consented
  - Consent (cfr previous)
  - Except :
  - If it is impossible to request specific consent on secondary use of MCH or, if this request would be inappropriate (by exception), secondary use can be granted by a positive advice issued by an Ethical Committee

Exception
presumed consent – opting out

- Residual HCM :
  - Is
  - Part of the HCM taken during procedures for diagnosis or treatment of the donor
  - Which
  - After a part is kept for diagnosis or treatment of the donor
  - Is redundant and will be destroy

Exception
presumed consent – opting out

- Consent for use of Residual HCM for research purposes is presumed as long as the donor does not oppose.

- The aimed use and the possibility to oppose must have been communicate in written to the donor, prior to the operation

- Any secondary use of this (Residual) HCM for scientific purposes, as well as the scientific aim must have been approved by an Ethical Committee.

Ethical Committee

- Relevance of the use of residual MCH
- Respect of the law and regulation (incl. Royal decrees)
- The adequacy of the information passed on and the specific and sufficient nature of the consent
- Impossible to ask for donor's consent…
  or inappropriate to ask

Controls

- Ethical Committee
  - creation of biobank , use of samples
- Federal agency of medicine and products of health (AFMPS / FAGG)
  - a biobank needs a notification

Hôpital Erasme

ULB