Legal framework – Biobanks in Belgium

CFE - FCE
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Overview

1. Flowchart
2. Legal framework – general overview
3. Donation and removal
4. Biobanks
   1. Basic requirements
   2. Storage entity – monopoly
   3. Traceability
   4. Biobank manager
   5. Supervision
5. Embryo research – EC approval, FCE control

1. Flowchart

Flowchart A

Supernumerary embryos/gametes

Biobank

Researcher

Flowchart B

Primary use –

gametes

Biobank

Researcher

1. Flowchart – where do these embryos come from?
2. Legal Framework – General overview

- Lex Generalis – Human Material Act
  - Exceptions – see art. 3, §4
  - Biobanks – royal decree 09/01/2018

- Lex Specialis:
  - Research on Embryos Act (11/05/2003)
    - Basic principles
    - Creation is possible, but only if objectives cannot be attained with supernumerary embryos
  - Medically Assisted Procreation Act (06/07/2007)
    - Regarding use of supernumerary gametes/embryos

3. Donation and Removal

- “Where do these embryos come from?”
  - Supernumerary embryo’s:
    - Possibility of research – contract with parents
    - After conservation period (5 years), or . . .
    - Desire for children fulfilled, or . . .
    - Deceased, divorced, etc.

- Voluntary, altruistic donation

- Informed consent – contract fertility centre
  - Can be revoked (until start of research project)
3.B. – Gametes

- Gametes:
  - Supernumerary:
    - Possibility of research – contract with parents
    - After conservation period (10 years), or . . .
    - Desire for children fulfilled, or . . .
    - Deceased, divorced, etc.
  - Donated specifically for research purposes ("Primary use")
    - See however: secondary use (Human material act 2008)

- Voluntary, altruistic donation

- Informed consent – contract fertility centre
  - Can be revoked (until start of research project)

3.C. – Consent – basic principles

- Informed:
  - Art. 10 Human Material Act 2008
  - Art. 8 Research on embryos act 2003
    - Legal requirements; removal technique; objectives, methodology and duration of the research or treatment; EC advice and, if relevant, FCE advice
  - Art. 7 AND 20 OR 49 MAP Act 2007.

- Written (same references)

- Specific:
  - Art. 10 Human material act 2008: not defined
  - Lex specialis: art. 8 Research on embryos act 2003 – "objectives, methodology and duration"

- Can be revoked
  - Lex specialis: art. 8 Research on embryos act 2003 – until start of research project

3.D. – Donation – Primary goal MAP?

- Gametes (and the resulting embryo’s)
  - Donated at hospital, under responsibility of a physician (art. 4, §2 Human Material Act 2008)
    - Exception – male gametes – can be donated/removed outside of hospital
  - Can only be acquired and stored at fertility centre
    - Art. 3, §4, 7th subparagraph Human Material Act 2008
    - See also (not related to Human Material Act 2008: AR/KB 15/02/1999 – Hospital program "Reproductive Medicine"
  - Donated specifically for research purposes ("Primary use"), if incorporated in contract with fertility centre
    - See however: secondary use (Human material Act 2008)

- Donation for research: voluntary, altruistic donation

- Contract fertility centre

3.D. – Donation – Primary goal research?

- Gametes (for creating embryos)
  - Donation can take place outside hospital:
    - Health, safety and discretion for donor required
    - By physician?
  - Can only be acquired and stored at fertility centre
    - Art. 3, §4, 7th subparagraph Human material act 2008
  - Donated specifically for research purposes ("Primary use")
    - See however: secondary use (Human Material Act 2008)

- Voluntary, altruistic donation

- Contract fertility centre
3.E. – Acquisition by or transfer to biobank

- Authorised laboratory (art. 3, 3° Research on embryos act 2003)
  - No "regular" biobanks
  - Same laboratory authorised to perform embryo research
- Transfer from fertility centre to biobank, after donation (see previous slides)
- Transfer directly from other donation site to biobank?
  - Human material act 2008: possible – art. 4, §1/1
  - However – MAP act 2007: intervention by fertility centre required – art. 49, references art. 7 and fertility centre explicitly, for donation.
- Informed consent – contract fertility centre
  - Can be revoked (until start of research project)

4.A. – Basic requirements

- Only authorised laboratory (art. 3, 3° Research on embryos act 2003)
  - Same laboratory authorised to perform embryo research
- No further prior authorisation by government
- EC approval of objectives and activities
  - "Fully authorised" EC – free to choose
  - (However: see under 5.)

4.A. – Basic requirements - notification

- Notification to FAMHP required
  - Address, contact information, etc.
  - Positive advice EC
  - Manager identity, diploma, contact information
- FAMHP: 15 days to request further information
  - 15 days for biobank to respond
- FAMHP:
  - 1. notification complete → notification number
  - 2. notification incomplete
    - Timely response and complete → notification number
    - No timely response → notification void
  - 3. no response from FAMHP? Notification accepted, number to be provided ASAP
4.B. Monopoly for storage

Stores human bodily material for research purposes
- Registry
  - Available for inspection at all times
- Written contract when material is used
  - Object
  - Traceability
  - Personal data?
    Written donor consent or proof that obligations regarding presumed consent are fulfilled

4.B. Monopoly for storage

Applicable to all human bodily material
- Stored or used in Belgium
- Acquired and transferred outside of Belgium

No direct transfer from hospital (or other location) to non-BE Biobank
- Art. 4, §2
- Further application: art. 8, §1, 5° - 7°; art. 8, §2/1

No direct transfer from non-BE Biobank to researcher
- Art. 8, §1, 5° - 7°; art. 8, §2/1

4.C. Traceability

Principle:
- Material can be traced from donor(s) to end-user (researcher)
- Requires coding/pseudonymisation
- Non-traceable material possible – (post-donation traceability nevertheless required)
  - Only for research purposes
  - However: non-traceable ≠ "anonymous" – GDPR . . .

4.D. Manager

Manager (beheerder/gestionnaire)
- Physician
- (Exception: pharmacist in case of non-traceable material)

Manager ensures
- Traceability (if applicable)
- Compliance with consent
  - Contract with end-user
- Compliance with EC-approval
4.E. Supervision

FAMHP
• Inspections regarding applicable legislation
• Mainly a posteriori – notification process only verifies if notification file has all required elements

Ethics Committees
• Biennial reporting
• Can revoke or alter positive advice
  • Procedure: intention to alter/revoke
    • 1 month for biobank to file an opposition, and/or CAPA-plan
    • 1 month for EC to decide

FCE?
• No new responsibilities.

5.A. Distribution to end user/researcher

Requires contract, must entail:
• Scope of the research project (link with consent/activities biobank)
• Traceability assurance and responsibilities
• Personal data? Appropriate technical/organizational measures
• (Other biobank? “coded copy” of the consent form)

Framework agreement possible, if:
• Researcher/end user contractually obligated to abide by the terms of this framework agreement;
• Entails, in general, the types of research for which the material may be used;
• Manager verifies, before distribution, specific project (consent, objectives)

5.A. End user/researcher

Receives material from biobank
• Can store and use material
• Must adhere to contract

No indefinite storage
• Would become a biobank

End of research project
• Material is returned
• Material is destroyed
5.A. End user/researcher

**Ethics committee approval?**
- Can be waived – Biobank’s EC approval applies

**However: lex specialis**
- Local (university hospital) EC approval always requires (art. 7 Research on embryos act 2003)
- FCE is consulted and can halt research project

5.B. In practice

**Only art. 3, 3° Research on embryos act laboratories can:**
- Conduct research on embryos
- Maintain a biobank

**Most likely: supplementary administrative tasks for laboratory**
- New role: “biobank manager” with specific tasks.

5.C. Flowchart – how do these laws affect our earlier flowchart?

- Consent can be revoked
- Deadline: start of research project

Embryo: donation at fertility centre
Ovocyte: donation at fertility centre
Sperm: donation under responsibility of fertility centre?
6. Conclusion

Biobank legislation will not add new intermediary:
• Art. 3, 3° laboratories will take up this role
• New: biobank manager, has certain responsibilities
• New obligations: maintain registry, biennial report to EC regarding objectives and activities of biobank
  • On top of yearly obligation for researchers to report to FCE

Most exceptions in Human material act 2008 are not applicable, or difficult to apply to embryos:
• Presumed consent post-mortem? Lex specialis overrules . . .
• Presumed consent for residuary material? Explicitly excluded
• Waiver for EC approval? Lex specialis overrules . . .
  • . . .