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 – where do these embryos come from?

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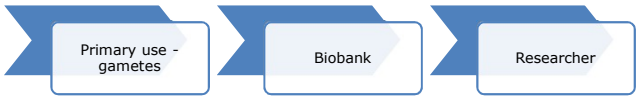
1. Flowchart

Flowchart A

Flowchart B



2. Legal Framework – General overview

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2. Embryo research – legal framework

- **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

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3.A. – Supernumerary embryos

- **"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. Biobanks

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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. Distribution and use

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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

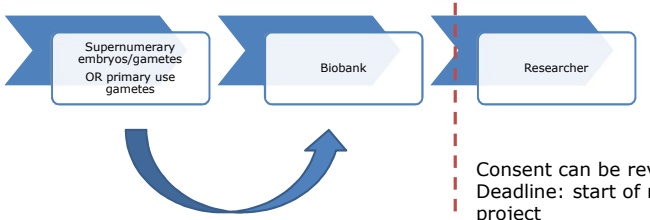
Only art. 3, 3° Research on embryos act laboratories can:

- 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?

In conclusion

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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 . . .
- . . .

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