Ethical issues in Biobanking

- Informed consent
- Confidentiality
- Financial issues
- Genetic Information
- Transparency & accountability
Ethical and legal issues

Dept. of pathology

Brain Bank

university

Dept. A

Dr. X

Institute

Global Pharmaceuticals

Dr. X Inc.

a network of excellence within the 6th framework programme of the European Commission
Ethical and legal issues

Based on the real events of the following cases:

- Canavan case (Greenberg vs. Miami Children’s Hospital), 2003.
- Alder Hay Scandal, United Kingdom.

Abstract of the cases can be found on BNE intranet website.
Ethical Dilemma’s and Legal issues in Brain Banking

A network of excellence within the 6th framework programme of the European Commission
Ethical and legal issues

BNE (BrainNet Europe)

FP6 consortium of 19 brain banks in 12 countries

AIM:
- Increase availability of tissue
- Harmonize diagnostic criteria
- Draft ethical and legal guidelines

a network of excellence within the 6th framework programme of the European Commission
Ethical and legal issues

---

cooking...

... like a Brit
available...

... as a Belgian

talkative... as a Finn

... humorous... as a German

patient...

... as a Luxembourger

flexible... as a Swede

... as an Austrian

organised...

... as a Spaniard

generous... as a Dutchman

... as a Greek

... as a Dane

... as the Irish

sober

... as a Portuguese

controlled...

... as an Italian

discreet...

... driving...

... like the French

technical...

a network of excellence within the 6th framework programme of the European Commission
Ethical and legal issues

Fundamental Ethical Principles

Ethical principles with regard to human beings:
• **Autonomy:**
  - Information and consent, free decision-making, freedom of thought.
• **Integrity**
  - Integrity of the human body, respect for human remains.
• **Confidentiality and privacy**
  - Personal information is entrusted and should be protected

Ethical principles with regard to organizations:
• **transparency and accountability**
Ethical and legal issues

Global Key Organizations on bioethics:

United Nations (UN)
- Universal Declaration of Human Rights
- Genetic privacy and non-discrimination

UN, (UNESCO Bioethics Program)
- Universal declaration on bioethics and human rights
- Universal declaration on human genetic data

World Health Organization (WHO)
- WHO Report for Consultation on Genetic Databases
- WHO Guidelines for Informed Consent for Uses of Human tissue for research

World Medical Association (WMA)
- Helsinki declaration
Ethical and legal issues

European organizations on Bioethics

Council of Europe (COE), Bioethics Department
- Convention for the Protection of Human Rights and Fundamental Freedoms
- Convention on Biomedicine (Oviedo)
- Additional protocols to the Convention on Biomedicine
- Rec. Research on biological materials of human origin (Draft Code of Conduct)

European Commission (EC) directives
- Personal Data Protection Directives:
- Dir 95/46/EC and Dir2002/58/EC
- Biotechnological inventions Directive (Dir 98/44/EC)

EGE of the EU: (European Group on Ethics in Science and New Technologies)
- Opinion to EC on Ethical Aspects of Human Tissue Banking
Ethical and legal issues

National organizations on Bioethics

NUFFIELD COUNCIL ON BIOETHICS

MRC Medical Research Council

HTA Human Tissue Authority

A network of excellence within the 6th framework programme of the European Commission
Our approach to the issues:

- Code of Conduct
- Model Brain Bank Regulations
  - Informed Consent Forms
  - MTA's
  - Confidentiality Agreement

Ethical principles
- Rules and guidelines
- Toolkit documents
Designing the Code of Conduct for Brain Banking

Counsel of Europe: Rec(2006) on research on biological materials of human origin

- Obtaining → Processing/Storing → Distributing
Ethical and legal issues

Code of Conduct

- Informed consent
- Data protection
- Authorization
- Autopsy
- Prohibition of financial gain
- Confidentiality
- Trans border flow
- Distribution and use of biological material
- Requests for material
- Research results
- Information on hereditary diseases
Ethical and legal issues

Code of Conduct

BNE Consortium
May 30th, 2008

A network of excellence within the 6th framework programme of the European Commission
Draft Model BBR (structure)

Chapter I: Organization, objectives, priorities, financing etc.

Chapter II: Procurement of tissue and data (informed consent)

Chapter III: Data protection and integrity

Chapter IV: Distribution of tissue and data to researchers

Chapter V: Organs and responsible persons
A network of excellence within the 6th framework programme of the European Commission

**Toolkit documents**

**Ethical and legal issues**

**HERSCHENDONATIE AAN DE NEDERLANDSE HERBANK**

**WAT U MOET WETEN**

We hebben over het wetenschappelijk onderzoek en de Nederlandse wetenschappers en de wetenschappelijke gemeenschap zowel in Nederland als in de Europese Unie een sterk netwerk van expertise. Dit netwerk is een basis voor het ontwikkelen van ethische richtlijnen en voor het creëren van een structuur voor het onderzoek in de wetenschap.

**Herschendonatie aan de Nederlandse Hersenkliniek**

**WILSONBEKWAAMHEID & DONORSCHAAP**

In het bekwaamheidsproject worden de volgende doelstellingen gezien:

1. DE NEDERLANDSE HERBANK
   - Nationaal netwerk van expertise
   - Ethische en juridische richtlijnen
   - Donorschap en documenten

2. Toolkit
   - Ethische en juridische richtlijnen
   - Donorschap en documenten

**BRAINNET EUROPE**

**TOESTAMMINGSFORMULIER NEDERLANDSE HERBANK**

**Dewijk, H.**

**Nederlandse Hersenkliniek**

**OVERZICHT KENNISNIVEAU**

- **Wilsonbekwaamheid & Donorschap**
  - Ethische en juridische richtlijnen
  - Donorschap en documenten

**INSTRUCTIES**

1. **Herschndonatie aan de Nederlandse Hersenkliniek**
   - Overzicht kennisniveau
   - Toolkit

2. **Ethische en juridische richtlijnen**
   - Donorschap en documenten

3. **Donorschap en documenten**
   - Ethische en juridische richtlijnen

4. **Toolkit**
   - Ethische en juridische richtlijnen
   - Donorschap en documenten

**NEDERLANDSE HERBANK**

**Herschndonatie aan de Nederlandse Hersenkliniek**

**WILSONBEKWAAMHEID & DONORSCHAAP**

In het bekwaamheidsproject worden de volgende doelstellingen gezien:

1. DE NEDERLANDSE HERBANK
   - Nationaal netwerk van expertise
   - Ethische en juridische richtlijnen
   - Donorschap en documenten

2. Toolkit
   - Ethische en juridische richtlijnen
   - Donorschap en documenten

**BRAINNET EUROPE**

**TOESTAMMINGSFORMULIER NEDERLANDSE HERBANK**

**Dewijk, H.**

**Nederlandse Hersenkliniek**

**OVERZICHT KENNISNIVEAU**

- **Wilsonbekwaamheid & Donorschap**
  - Ethische en juridische richtlijnen
  - Donorschap en documenten

**INSTRUCTIES**

1. **Herschndonatie aan de Nederlandse Hersenkliniek**
   - Overzicht kennisniveau
   - Toolkit

2. **Ethische en juridische richtlijnen**
   - Donorschap en documenten

3. **Donorschap en documenten**
   - Ethische en juridische richtlijnen

4. **Toolkit**
   - Ethische en juridische richtlijnen
   - Donorschap en documenten
Ethical and legal issues

Ethical principles in the Code of Conduct

1. Personal autonomy and informed consent
2. Confidentiality
3. Non-commerciality
4. Transparency and accountability
5. Quality
Ethical and legal issues

Informed Consent / Authorization

A network of excellence within the 6th framework programme of the European Commission
Ethical and legal issues

a network of excellence within the 6th framework programme of the European Commission
Ethical and legal issues

Inquiry finds brains were removed without consent

BMJ VOLUME 326 17 MAY 2003

a network of excellence within the 6th framework programme of the European Commission
### Ethical and legal issues

#### Why informed consent?

**Ethical arguments**
- Ethical duty
- Public trust
- Goodwill
- Increasing public awareness
- Donor program
- Learn from the scandals

**Legal arguments**
- Human right of autonomy and self-determination
- MD’s (including pathologist) duty of care
- Legal entitlement to Material
- Facilitating transborder collaborations
- Industrial partners
- Patenting of inventions
- Anticipation on legislation

---

A network of excellence within the 6th framework programme of the European Commission
Ethical and legal issues

Neurological or psychiatric disorder leading to incompetence to make personal decisions.

Implications for Consent and Authorization

Source: Based on poster of Foundation Alzheimer Disease Netherlands
I swear by Apollo Physician and Asclepius and Hygieia and Panaceia and all the gods and goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant:

“What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about.”

Par. (26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law;
Human tissue research plays a vital role in developing a deeper understanding of human disease processes and their underlying mechanisms.

Studying changes at the molecular and cellular level in human tissue makes it possible to relate the patient’s symptoms to the disease processes (pathology). This in turn increases the likelihood of effective new medicines being developed to treat diseases that currently are either poorly treated (such as osteoarthritis) or do not have suitable treatments (such as multiple sclerosis).

Human tissue is used to predict the likely effectiveness of a potential new medicine and to identify some of the possible unwanted effects. It is valuable, therefore, in the drug discovery process by enabling earlier and better predictions about the effectiveness and safety of a new compound.

AstraZeneca supports robust international legislation and ethical guidelines, and we have policies and processes in place to ensure that donated tissue is handled in a highly responsible and ethical manner. This places emphasis on the principles of informed consent, designed to protect the rights and expectations of donors and families, whilst enabling an environment in which important medical research can flourish.

In line with our Bioethics Policy, we have established processes that cover the acquisition, use, storage and disposal of human tissue samples that are used in our human tissue research. Central to these processes is our endorsement of the internationally accepted ‘gold’ standard that requires human tissue samples to be obtained only with the approval of an independent ethics committee, and with the fully informed consent of the donor (or their appointed representative). Supplier and collaborator evaluation are also an essential aspect of our policy. To maintain best practice, we continue to develop and refine these processes and apply them through on-going education, training, monitoring and assessment programmes for employees, suppliers and collaborators.
Ethical and legal issues

A network of excellence within the 6th framework programme of the European Commission

1. DNA structure
2. SNP

Apolipoprotein E (ApoE) is a protein that helps carry cholesterol in the blood. Two common forms of this protein are ApoE2 and ApoE4. ApoE4 is associated with a higher risk of Alzheimer's disease.

- Families (sixth-six)
- Sporadic Cases/Unrelated Controls
  - Affected: 150
  - Unaffected: 197, 103, 152

ApoE4 contains a single nucleotide polymorphism (SNP) at position 192. In this SNP, the allele C is associated with a higher risk of Alzheimer's disease compared to the allele T.
Ethical and legal issues

Costs and income of the Brain Bank

Costly activities:
• Donor program
• Rapid autopsy
• Fresh dissection protocol
• Summary of medical data
• Many tissue applicants
• Specialized characterization

Income:
• Structural funding
• Grants
• Charities
• Subsidies (government)
• Income from users
  i. non-profit users
  ii. for-profit users

* a network of excellence within the 6th framework programme of the european commission
Ethical and legal issues

a network of excellence within the 6th framework programme of the European Commission
Ethical and legal issues

Home -> Tissue Related -> Human Adult Normal -> Frozen Tissue Microarray

Human FDA/CE Standard Normal Frozen Tissue Array (30 different human normal tissues, 3 different donors each) (90 cases 90 cores)

Cat#: T6234701-1-BC
Quantity: Set of 2 slides
Price: 998 EUR
Supplier: Biochain

Data Sheet
Ethical and legal issues

Netherlands Brain Bank
  • Natasja Klioueva
  • Marleen Rademaker
  • Inge Huitinga

VUmc Amsterdam:
  • Annemieke Rozemuller

University of Amsterdam:
  • Sjef Gevers

With special thanks to:
  Thomas Arzberger (Munich)
  Tamas Revesz (London)
  James Ironside (Edinburgh)
  Peer Schmitz (Munich)
  Safa Al-Saraj (London)
  David Dexter (London)
  Richard Reynolds (London)
  Jeanne Bell (Edinburg)

www.brainbank.nl

A network of excellence within the 6th framework programme of the European Commission