

## List of abbreviations

### 1. Introduction

- 1.1. From clinical to clinico-genomic research: New ethical and legal challenges
- 1.2. The ACGT project: Developing an ICT infrastructure
- 1.3. Aim and structure of the book

### 2. Ethical requirements

#### 2.1. Introduction

#### 2.2. Informed consent

##### 2.2.1. Ethical foundations of the doctrine of informed consent

###### 2.2.1.1. Historical background

###### 2.2.1.2. General aspects

###### 2.2.1.3. Informed consent in tissue-based research

##### 2.2.2. The scope of consent

###### 2.2.2.1. Models of consent

###### 2.2.2.1.1. Specified consent

###### 2.2.2.1.2. Broad or blanket consent for future research

###### 2.2.2.1.3. Tiered consent models

###### 2.2.2.1.4. Patients and donors perspectives

###### 2.2.2.1.5. Particularities of consent to research involving children

##### 2.2.2.2. Informed consent and communication

###### 2.2.2.2.1. The character of information

###### 2.2.2.3. Issues to be consented to

###### 2.2.2.3.1. General requirements

###### 2.2.2.3.2. Sharing data and information

###### 2.2.2.3.3. Re-contact

###### 2.2.2.3.4. Commercial interests

###### 2.2.2.3.5. The timeframe of consent

##### 2.2.2.4. The right to withdraw consent

### 2.3. The right to know, the duty to inform, and the quality of feedback

#### 2.3.1. Access to personal information: a donor driven inquiry process

#### 2.3.2. Feedback of research results: an investigator driven disclosure process

##### 2.3.2.1. Informing about general research results

###### 2.3.2.1.1. Ethical foundations

###### 2.3.2.1.2. Practical challenges of feedback processes regarding general research results

###### 2.3.2.2. Information about individually relevant research results

###### 2.3.2.2.1. Ethical foundations

###### 2.3.2.2.2. What to feed back?

###### 2.3.2.2.3. Characteristics of genetic research results in the context of cancer trials

###### 2.3.2.2.4. To whom to feed back?

###### 2.3.2.2.5. Practical challenges of feedback processes regarding individual research results

### 2.4. Summary of consolidated ethical requirements

#### 2.4.1. Ethical requirements

##### 2.4.1.1. Summary: The informed consent process

##### 2.4.1.2. Conclusions: How to design the informed consent process

##### 2.4.1.3. Summary: Donor driven inquiry processes and investigator driven individual feedback processes

##### 2.4.1.4. Conclusion: How to organize donor driven inquiry processes and investigator driven individual feedback processes

### 2.5. Outlook: Ethical challenges in the European context

#### 2.5.1.1. Revision of data protection and information flows

#### 2.5.1.2. Community interests

### 3. Legal requirements

#### 3.1. Introduction

#### 3.2. Theoretical analysis

##### 3.2.1. European Data Protection Directive 95/46/EC

###### 3.2.1.1. Genesis

###### 3.2.1.2. Scope of the Directive

###### 3.2.1.2.1. Personal data

###### 3.2.1.2.1.1. Anonymous data

###### 3.2.1.2.1.2. Pseudonymous data

###### 3.2.1.2.2. Territorial application

##### 3.2.1.3. Fair and lawful data processing

###### 3.2.1.3.1. General

###### 3.2.1.3.1.1. Requirement of a legal basis

###### 3.2.1.3.1.2. Technical and organisational measures

###### 3.2.1.3.2. Sensitive data

###### 3.2.1.3.2.1. Definition

###### 3.2.1.3.2.2. Prohibition of data processing

###### 3.2.1.3.2.3. Exceptions

##### 3.2.1.4. Duties of the data controller

##### 3.2.1.5. Rights of the data subject

- 3.2.1.5.1. Information duties regarding data collection from the data subject
- 3.2.1.5.2. Information duties regarding data which has not been obtained from the data subject
- 3.2.1.5.3 Right of access
- 3.2.1.5.4. Right to rectification, erasure or blocking
- 3.2.1.5.5. Exemptions and restrictions
- 3.2.1.5.6. Right to object
- 3.2.1.6. Transfer of personal data to third countries
- 3.3 Data protection within a trans-european research project . using the example of ACGT
- 3.3.1. Data flows
- 3.3.2. Legitimate processing of genetic data (Directive 95/46 EC)
- 3.3.2.1. Genetic data
- 3.3.2.1.1. Special characteristics of genetic data with regard to data protection
- 3.3.2.1.2. Anonymisation of genetic data
- 3.3.2.2. Relevance of the character of data processing for the distinction between personal data and anonymous data
- 3.4. Data protection framework within genetic research networks
- 3.4.1. Anonymisation of genetic data within research networks
- 3.4.2. Necessary legal agreements, contracts and informed consents
- 3.4.2.1. Contract between the Data Protection Authority and the data exporter (e.g. a hospital)
- 3.4.2.1.1. Guarantee of a %state-of- the-art+pseudonymisation
- 3.4.2.1.2. Technically and organisationally separated project database
- 3.4.2.2. Contract between Data Protection Authority and end users
- 3.4.2.2.1. Data controllers within genetic research networks
- 3.4.2.2.2. Data Protection Authority as central Data Protection Authority within the research network
- 3.4.2.2.3. Ensuring the context of anonymity
- 3.4.2.2.4. Separated database
- 3.4.2.2.5. No matching
- 3.4.2.3. Second pillar and first fallback scenario: Informed Consent
- 3.4.2.3.1. Regulatory framework
- 3.4.2.3.1.1. Definition
- 3.4.2.3.1.2. Declaration of intention
- 3.4.2.3.1.3. Freely given
- 3.4.2.3.1.4. For a specific case
- 3.4.2.3.1.5. Informed indication
- 3.4.2.3.2. Scope of the consent
- 3.4.2.3.2.1. Object of the consent/purpose specification/future research
- 3.4.2.3.2.2. Expected period of usage/temporal scope of the consent
- 3.4.2.3.2.3. Death of the patient
- 3.4.2.3.2.4. Data transfer to third parties/third countries
- 3.4.2.3.3. Consent of relatives needed?
- 3.4.2.3.3.1. Additional information of relatives is collected
- 3.4.2.3.3.2. No additional information of relatives is collected
- 3.4.2.3.4. Consent of the minor data subject or person with intellectual disabilities needed?
- 3.4.2.3.5. The right to withdraw and right to erasure
- 3.4.2.4. The right to know and the duty of notification
- 3.4.2.5. Third Pillar and second fallback scenario: Exceptions for genetic research in national legislations
- 4. Legal conclusion
- 5. References
- 6. Appendix 1. legal terminology
- 7. Appendix 2 . relevant regulation