Model Brain Bank Regulations

BNE Consortium
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Purpose of the BBR

The guidelines and recommendations currently in use, such as Draft Guidelines for Human Biobanks and Genetic Research Databases by OECD or Recommendation by the Council of Europe (Rec 2005, CoE), instruct new and established biobanks and tissue repositories to:

- Clearly define their objectives,
- Describe their organizational structure,
- Communicate policies and standard operating procedures.

Although many of these instructions are frequently put into practice, only few tissue repositories have put them in writing.

When a Brain Bank aims for establishment and further professionalization, an internal Regulations document is indispensable. Such a document is an enduring reference regarding organizational governance. Regulations should be easily accessible to donors, scientists and other stakeholders.

Following the agreements established by ratification of the Code of Conduct and other guidelines for research biobanks, we have prepared a Model Brain Bank Regulations. This document is **not a guideline**, such as many prepared by other (more authoritative) instances, but a **translation of guidelines** into practice.

The Model BBR is **a framework**, which ought to be enriched with content according to the individual situation of the local Brain Bank. The document is to be adopted 'at will' by the Brain Bank.

Contents

CHAPTER I

With regard to the organization of the Brain Bank

DEFINITIONS, OBJECT, SCOPE, BRAIN BANK ORGANIZATION, PURPOSE, ACTIVITIES, REPORTING

Article 1 Definitions

BrainNet Europe II-project
Sixth Framework project BrainNet Europe II, funded by the European Commission under contract number LSHM-CT-2004-503039.

Consortium Agreement
Agreement signed on November 20, 2003 between participants in the BrainNet Europe II-project, by which the BNE Consortium was established.

BNE Consortium Partners
Partners of the BNE Consortium, who conduct Brain Banking Activities.

Associated Partners
Allied partners without voting rights, who may participate in meetings and in the activities of the BNE Consortium without liability to the European Commission and without contractual duties.

Brain Banking/ Brain Bank Activities
Activities such as obtaining, handling, processing, storing and distributing Material and Data, including all associated research activities.

Informed Consent
Informed, free, express and documented decision to donate Material and Data for scientific research or other purposes.

Human Biological Material
Human Biological Material including:

i. Tissues: brain and meninges, pituitary, spinal cord, peripheral nervous tissue and other tissues adjacent to the nervous system such as muscles, lymph nodes and blood vessels;
ii. Fluids: such as cerebrospinal fluid or blood;
iii. Cells derived from all of the above-mentioned, including their progeny and unmodified derivatives.

Authorization
Informed Consent given by a legal representative or the next of kin on behalf of a person unable to give Informed Consent.

Brain Donation Program
A program where an individual can record his or her intent for donation, or provide Informed Consent or provide Authorization for post-mortem donation of the Material and Data to the Brain Bank.

Donor
The source of the Biological Material.

Material and Data
Any Human Biological Material and Donor-related Data.

Directly Identifying Material or Data.
Any Material or any Data which, alone or in combination with associated information, allow identification of the person concerned without disproportionate efforts.

Pseudo Anonymized / Coded Material or Data.
Any Material or any Data which allows identification of the person concerned by authorized individuals only through the use of a key.

Fully Anonymized / Unidentifying Material or Data
Any Biological Material or Data which alone or in combination with associated information does not allow identification of the person concerned, without disproportionate efforts.

Information on Hereditary Diseases
Any information which is either predictive of genetic disease or can serve to identify the person as a carrier of a gene responsible for a disease or detect a genetic predisposition or susceptibility to a disease, when scientific proof for validity of that information is present.

Data Processing Equipment
All equipment that reads or writes data from or to digital media.

Data Communication Equipment
All equipment that allows the transport of data to, from or across any local or remote digital network.

Tissue Finder / Tissue Finder Database
An online database built to facilitate Material exchange among the BNE Consortium Partners. The Tissue Finder Database contains descriptions of cases and material available at the individual Brain Banks of the BNE Partners. Data stored in the Tissue Finder Database is either Pseudo Anonymized or Fully Anonymized and does not, with reasonable efforts, allow identification of the Donors by anyone searching the Database. The Tissue Finder Database is only accessible to the Partners of the BNE Consortium, and only via encrypted internet. Partners can search for and place requests for Material, which may or may not be granted.

BNE Request Form
Online form by means of which researchers can submit a request for Material and data to the BNE Consortium.

Removable Data Media or Removable Data Storage Media
Any removable media such as USB sticks, floppy disks, tapes, CDs, DVDs that store data not for the specific purposes of backing up data.

Backup media
Any removable media such as tapes, CDs, DVDs, USB sticks, floppy disks that store data for the specific purpose of backing up data.

Encryption
Disk Encryption - a process by which hard disk information is encrypted on the disk itself and can only be decrypted by the use of the relevant password. If the password is not given, the disk will only show encrypted data.

Network Encryption - a process by which transmitted digital data is not sent "in the clear" but encrypted to render eavesdropping more difficult. Also referred to as https or "Secure Servers".

System logging
A process by which a date, time, originator and action of a user are logged in a logfile, thereby establishing retraceability and allowing systems administrators to retrace what happened to information should such a search be deemed necessary.

Internal or Local Network
Internal or Local Network - the collection of Computers and Communications cables inside the confines of the Brain Bank.

External Network
External Network - the collection of Computers and Communications cables outside the confines of the Brain Bank (such as the Internet).

Network surveillance tools
Software that allows administrator to observe what actually happens on the cable or network by employing eavesdropping techniques (e.g. Snooper is a commonly employed Network sniffing software alerting administrators to potentially dangerous unwarranted intrusions).

Data subject
Living person whose personal information is collected and processed.

Access
Any access to material and data including

i. Physical access including access to filing cabinets, archives, freezers, storage rooms where Data or Material are stored; collectively referred to as Physical Access;
ii. Electronic access such as access to electronic files, databases, systems, networks; collectively referred to as Electronic Access.

Commercial exploitation
The sale, lease or commercial licensing of the Material. Commercial exploitation also includes uses of the Material to produce or manufacture products for general sale.

Article 2 Object of the Brain Bank Regulations (BBR)

Regulations should firstly state its own purpose. The question why there is a need for internal regulations of the Brain Bank is answered in this article.

Article 2 Object of the Brain Bank Regulations

These Regulations are adopted by the <BB> in order to:

1. elaborate on the ethical principles laid down in the Code of Conduct of the BNE Consortium;
2. describe the organization of the <BB>;
3. specify the purpose and objectives of the <BB>;
4. define the policies of the <BB>;
5. state the guidelines the <BB> adheres to and
6. […] and […].

Article 3 Scope

The activities that fall within the scope of the BBR should be specified. For example the scope of the Regulations can be broadened to staff of the contracted laboratory or limited to the employees of the Brain Bank only.

Article 3 Scope

Paragraph 1
These Regulations shall apply to all Brain Banking and related research activities carried out within the <BB>.

Paragraph 2
These Regulations [or certain articles or certain chapters] shall [equally] or [under certain conditions] apply to <name persons or organization>.

Article 4 Modification

The draft guidelines by OECD (see art. 3.6) emphasize that biobanks should anticipate the need for modification of their policies, protocols and procedures. The Brain Bank should have in place a process for undertaking these modifications within its structure.

Article 4 Modification

Paragraph 1
These Regulations shall be revised every [period], by [organ], in consultation with [organ].

Paragraph 2
[Articles number and number] shall be revised every [period], by [...].

Article 5 <BB> organization

The structure of the organization of the Brain Bank should be described in accordance with principles of transparency and accountability.

Article 5 <BB> organization

Paragraph 1
The <BB> [does not] possess legal personality. The <BB> is a department of the <name institute or department> which is a <name entity> of the <organization which is a legal entity>. <Organization which is a legal entity> is a <public or private> legal entity, established by <law or act> having its registered seat at <address>.

Paragraph 2
The <BB> name and logo are meant to acquire public acknowledgement and to promote the Brain Bank.

Article 6 The purpose of the <BB>

In compliance with art. 14 par. 2 of Rec 2005(4) of the CoE (CDBI) and EC Directive 95/46/EC the purposes of collection of human biological material and personal data should be specified.

Art. 2A of the OECD guidelines stipulate that both current and future purposes of human tissue banks should be clearly formulated, and communicated as early and as widely as possible, especially to potential participants (donors) and potential users.

Article 6 The purpose of the <BB>

The purpose of the <BB> is to facilitate scientific research by distributing well-documented human material among researchers conducting scientific research in the field of neuroscience.

Article 7 The objectives of the <BB>

In compliance with art. 2A Draft Guidelines of OECD the objectives should be clearly formulated.

The question of who decides upon the objectives of the Brain Bank and whether such decisions need to be taken in consultation with or with the approval of certain bodies, such as an institute's board of directors or donor representatives, should be carefully considered.

Article 7 The objectives of the <BB>

Paragraph 1
The objectives of the <BB> are:

1. the distribution of well-documented high quality material to scientific researchers;
2. increasing public awareness of the importance of the use of human tissues for scientific research on brain function and disease;
3. [..] and [..].

Paragraph 2
The objectives are decided upon by <organ or organization> in consultation with <organ or organization> and <donor representatives>.

Paragraph 3
The objectives are made public by the means of <…>.

Article 8 The priorities of the <BB>

Priorities are the short-term objectives, and should always be in line with the objectives and purpose of the Brain Bank, as stated in the previous articles. Priorities of the Brain Bank should also be considered in relation to the available funds (income), manpower and conditions set by the stakeholders and funders.

The question of who decides upon the priorities of the Brain Bank and whether such decisions need to be taken in consultation with or with the approval of certain bodies (for example donor representatives) needs careful consideration.

Clear priorities will prevent unnecessary accumulation of unused tissue.

Priorities laid down in the regulations should function as terms of reference for accepting or denying any request for material. Also see article on Evaluation of Requests, Chapter IV.

Article 8 The priorities of the <BB>

Paragraph 1
Priorities of the <BB> are decided upon by <persons, organ or organization>, in consultation with <person, organ or organization>.

Paragraph 2
The priorities of the Brain Bank are announced by means of <…>, every <period>.

Paragraph 3
As from this date, the priorities of the <BB> are:

- to expand the collection of <disease groups>;
- to expand the collection of control subjects;
- to optimize and refine the neuropathological characterization of the tissue;
- to increase the standardization of the coded clinical summary of the donors;
- bioinformatics analysis of the databases;
- to strive for financial sustainability, stability and continuity of the organization>;
- <customization of services, in order to avoid unused tissue accumulation>.

Article 9 Activities of the <BB>

The activities of the Brain Bank should be in line with its objectives and priorities.

If certain activities are performed externally this may be specified in this article by inserting the words [subcontracted] before the relevant activity. The legal basis of such activities needs to be characterized in terms of scientific collaboration, contracted service, voluntary work and so on. In case of subcontracting, the conditions, including the requirements to the subcontractor, should be addressed. Written appointments, contracts and agreements with service providers should be in place.

Article 9 Activities of the <BB>

In accordance with its purpose and objectives the <BB> performs the following activities:

i. recruitment of donors and provision of information about Brain Banking;
ii. donor follow-up;
iii. obtaining and documenting Informed Consent or Authorization;
iv. Material retrieval, by means of [cranial] autopsy;
v. neuropathological and other examination of the retrieved Material;
vi. documenting and anonymizing donor Material and related data <e.g. by making “Minimal Clinical Data Set”>;
vii. storing Material and Data;
viii. reviewing applications for research Material;
ix. distributing Material on the basis of approved applications or <providing access to researchers to Material and Data>.
x. processing post-mortem Material to render it suitable for research purposes.

Article 10 Financing

The Brain Bank should be transparent about the sources of its income. Equally the conditions under which the funds are provided should be clearly established. In certain cases approval of the parent organization will be required to receive funds. Issues connected with surplus income and deficits need to be addressed.

Article 10 Financing

Paragraph 1
Neither the <BB> nor its affiliated institutions intend to make a profit.

Paragraph 2
The income of the <BB> consists of:

1. the capital of the <Trust, Foundation etc>;
2. governmental subsidies;
3. <contributions made by the European Commission>;
4. grants by <...>;
5. financial contributions by the researchers;
6. amounts which are or will be obtained through donations, testamentary depositions <etc>.

Paragraph 3
All income mentioned under paragraph 1 received in any year by the <BB>, under whatever name, which is not intended to be set aside as capital, shall be used for the activities and accomplishment of the objectives of the <BB>, in line with the priorities of the <BB>.

Paragraph 4
If in any year the funds available for the accomplishment of the objectives are only partly used, the <organ> determines whether and to what extent the balance not used will be <in what way used> or <reserved for the future accomplishment of the objectives of the BB>.

Paragraph 5
If in any year the income of the <BB> falls short of its costs <specify how the deficits will be covered>.

Paragraph 6
If the deficits are structural <specify how these structural deficits will be covered>.

Article 11 [Permissions to operate]/ [approvals]

The licenses, registrations, ethical approvals which the Brain Bank has been granted or needs to hold can be specified here.

Article 11 [Permissions to operate]/ [approvals]

The <BB> is registered at [...] or holds [licenses, approval, registrations], which <should

be/are renewed every period>.

Article 12 Reporting

Article 12 Reporting

Paragraph 1
Annually the <BB> reports to [person, organization].

Paragraph 2
Annually the <BB> will publish a progress report on activities.

Paragraph 3
The financial statement of the <<BB> shall be included in the annual report of the Legal Entity>.

Article 13 Cessation of all Brain Banking activities and succession of the resources

Provisions in case of cessation of all Brain Banking should be included in the BBR.

Article 13 Cessation of all Brain Banking activities and succession of the resources

Paragraph 1
<Organ or person>, in consultation with donor representatives and other stakeholders, may make decisions on cessation of all or part of the Brain Banking activities. Plans to terminate all Brain Banking activities and a call for succession, including any eligibility criteria, will be announced, upon such a decision.

Paragraph 2
<Organ or person> in conformity with paragraph 1, shall consider all eligible organizations for the succession of all Brain Banking activities, including the Donor Program.

Paragraph 3
Succession shall be formalized by a transfer agreement signed by both parties, upon which all Material and Data stored at the <BB>, [including all donor registrations] and material transfer agreements shall be transferred to the successor, subject to acceptance of provisions of these Regulations or similar provisions for the governance and management of the succeeded resources.

Paragraph 4
In case no suitable successor is available, all Material and Data stored at the <BB> shall be irreversibly destroyed. All Donors registered at the donor program will receive written notification of the cessation of all Brain Banking activities.

Paragraph 5
Upon succession as specified in paragraph 3 or termination as specified in paragraph 4, the <BB> will cease to exist.

CHAPTER II

With regard to obtaining the Biological Material and Data

INFORMATION, REGISTRATION, INFORMED CONSENT AND AUTHORIZATION

Article 14 Procurement

This article describes how material stored in the Brain Bank is procured.

Article 14 Procurement (please see the clarifications in the boxes below)

Paragraph 1
The Material stored in the <BB> is obtained through:

1. cranial autopsies carried out in accordance with Informed Consent or Authorization, in the framework of a Donor Program;
2. clinical autopsies carried out in accordance with <specify law, act or regulation>;
3. autopsies performed on the instructions of the [medico-legal authority], carried out in accordance with <specify law, act or regulation>;
4. material referred for diagnostics from [specify procedures] and retained for research purposes <with appropriate consent> and in accordance with <specify law, act or regulation>;
5. Material obtained in the framework of diagnostic procedure carried out on a living patient and retained for research purposes in accordance with <appropriate consent procedure> and <law, act or regulation>.

Paragraph 2
The autopsies are carried out at <location/ institution>, by <professionals> [licensed / registered] in accordance with <law, act or regulation>.

Clarifications to art. 14
With regard to Paragraph 1 sub 3: the fact that in some cases autopsy does not require consent or authorization, for example medico-legal autopsy or routine hospital autopsy, does not mean exemption of prior consent of the deceased or authorization by the next of kin regarding the use of the Material or Data for research purposes.. The right to give consent or authorization cannot be unilaterally assumed by the legal authority or medical doctor ordering an autopsy. Consequently objection to the use of organs for research cannot be overridden by an order of authority, physician or pathologist.

Article 15 Donors of the Biological Material

The donors (sources of the Material collected and stored by the Brain Bank) should be specified here.

Article 15 Donors of the Biological Material

The Material stored in the <BB> is obtained from:

1. deceased Donors who during life voluntarily registered as a donor at the <BB/

Donor Program> by means of an Informed Consent;
2. deceased incompetent Donors who are registered as a Donor at the <BB> and on whose part an Authorization has been given by the legal representative or the next of kin;
3. deceased Donors, after a post-mortem Authorization has been obtained from the next of kin;
4. deceased persons subjected to a post-mortem examination, after which Material originally obtained for diagnostic purposes has been retained for research purposes;
5. living persons whose biological Material removed during diagnostic procedure or therapeutic intervention has been retained for research purposes.
6. <>;
7. <>.

Article 16 Guideline on obtaining Informed Consent or Authorization

This article contains a guideline for the kind of information to be made available to the potential donors (i.e. Informed consent), representatives and the next of kin (i.e. Authorization). It has been drafted in accordance with and in analogy to the guidelines produced by WHO and HTA.

The concept of informed consent should have a prominent role in Brain Banking. Interactions between Brain Bank and donors, their next of kin or representatives should be perceived as quality parameters for the work of the Brain Bank. In case of cessation of Brain Banking activities as set out in art. 13 Cessation and Succession, Chapter I, compliance with this guideline should be set as indisputable condition for the succession of Brain Bank's resources.

Article 16 Guideline on obtaining Informed Consent or Authorization

(please also regard clarifications below the box)

Paragraph 1
The following information should be made available to the person prior to signing an Informed Consent or Authorization, as mentioned in Article 15:

a. information regarding organization <BB/ institution/ legal entity> collecting human Biological Material, including information on Ethical approvals and permissions to operate from Relevant Authorities;

b. purposes for which the Material and Data are collected;

c. purpose of the registration at the Brain Bank;

d. eligibility for registration;

e. possibilities to place restrictions on the scope of the Informed Consent or Authorization;

f. the right to withdraw Informed Consent or Authorization at any time, and the consequences of withdrawal;

g. eligibility and procedure of autopsy in order to obtain the Material for research and

the risks associated with autopsy;

h. nature and amount of samples of Material to be taken, organs to be removed during autopsy and choices in that respect;

i. nature and amount of personal data which will be collected and choices in that respect;

j. where the Material and Data will be stored and relevant security arrangements;

k. who will have access to the Material;

l. on what conditions the Material will be distributed;

m. how long the Material and Data will be kept;

n. the arrangements for disposal of the Material and choices in that respect;

o. whether the (general) results on research will be communicated to the family of the deceased;

p. whenever required [whether autopsy or research with Material is expected to generate information which is predictive of genetic disease or which serves either to identify the person as a carrier of a gene responsible for a disease and choices in that respect;]

r. <other>

Clarifications to art. 16 paragraph 1

a. and b. It should be clear to the (prospective) donor, what organization is collecting the Material and Data and for what purpose. When and where appropriate it should be specified what use the donated material will be put to (e.g. research, education).

c. The purposes and the consequences of the registration should be particularly clearly addressed when it concerns registration for a donor program.

e. and f. In accordance with art. 12 of the Code of Conduct a person signing Informed Consent or Authorization has the right to place restrictions, alter the scope or fully withdraw consent. No restrictions can be placed upon these rights. Consent or Authorization withdrawal must not lead to any adverse consequences for the person concerned. It is advised to include the following statement in the consent forms: "withdrawing consent will not affect your medical treatment in any way". The person should be informed of whom to contact in order to withdraw the Informed Consent or Authorization.

g. and f. Unlike clinical or medico-legal autopsies, donor programs offer excellent possibilities for selection. Selection criteria however need to be sensitively addressed in the consent forms. It is disputable how much information on the procedure of the autopsy should be provided. Under all circumstances all questions asked should be attended with appropriate sensitivity and openness. Risks associated with the autopsy (sutures), should be addressed.

h. The person signing Consent or Authorization should be informed about what exactly is going to be removed and stored at the Brain Bank. Whenever possible the person must be offered a number of choices, It is advisable to include boxes in the consent form which the person has to check in order to indicate what can be removed: small samples, whole brain, spinal cord, etc);

i. and j. It should be clear where the Material and Data shall be stored. Person should be informed that a Brain Bank is a secure environment and that Material is stored and distributed anonymized. When desired, further information on security arrangements should be made available (please see Chapter III on Data Protection);

m. Consider the legal restrictions regarding the length of the period during which the medical dossier or biosamples may be retained;

n. Consider whether it is possible to return samples to the family for funeral arrangements, when the family requests it.

o. General results may include research performed/publications arising from research.

p. Further consequences of such information for the health of the persons related to the donor; risks connected to knowing such information, risks regarding employability and insurability. Arrangements which have been made to provide genetic counselling and due care.

r. For example, the possibility of commercial value/intellectual property benefit should be disclosed.

Article 16 Guideline on obtaining Informed Consent or Authorization

(please also see the clarification below the box)

Paragraph 2
Informed Consent or Authorization signed by the person in accordance with sub a, b and c, should <shall> explicitly cover the following elements:

a. (when required) consent to perform post-mortem autopsy;

b. consent to remove and to retain indicated organs, tissues and fluids (the Material) and to use them for research (or other indicated purposes);

c. possibility to place restrictions on the scope of the Informed Consent or Authorization;

d. permission to view medical records and to process data contained therein;

e. statement that the prospective Donor, representative or next of kin understands that Informed Consent or Authorization can be withdrawn at any time and how this should be done;

f. [where appropriate] permission to feedback the information on post-mortem diagnostics to the family;

g. when Authorization on behalf of the deceased person is signed by a representative or by the next of kin, a statement that to the knowledge of the representative or the next of kin no objection to post-mortem donation for research purposes or similar objection has been previously made by the deceased;

h. consent to perform research which could generate genetic information.

Clarification to art. 16 paragraph 2
The consent or Authorization form is a legal document, the formulation of which should explicitly cover certain points. Consent or Authorization forms are the evidence of legitimate acquisition of the Material, and can be used for the purposes of audits, transfer to abroad and so on.

Article 16 Guideline on obtaining Informed Consent or Authorization (continuation)

Paragraph 3
Persons involved in the consent process should be provided with the opportunity to communicate with representatives of the <BB>.

Paragraph 4
When required <when appropriate> Informed Consent should be co-signed by the next of kin, a confidant or a witness of the donor.

Paragraph 5
When required <when appropriate> post-mortem assent of the next of kin should be obtained.

Article 17 Special considerations in case of Incompetent Persons

This article has been drafted in consideration of art. 14 par 3 of the Convention on Biomedicine and in accordance with art. 10 of the Code of Conduct.

Article 17 Special considerations in case of Incompetent Persons

(please see the clarifications below the box)

Paragraph 1
Biological Materials obtained from the deceased persons who during their life were incapable of providing Informed Consent, shall only be used in the research project subject to conditions stated in art. 10 of the BNE Code of Conduct.

Paragraph 2
When Authorization for registration with a Donor Program is given by a representative on behalf of an incompetent person in accordance with Article 15 sub 2, the following should be taken into consideration:

1. whether all legal requirements for Authorization are satisfied;
2. whether the person signing Authorization has the powers of representation of the incompetent persons and what the grounds of such powers are;
3. that the representative has the obligation to act in the best interest of the incompetent person;
4. whether evidence is present that prior to becoming incompetent the person was expressly opposed to post-mortem donation for scientific research;
5. whether it is justified to verify incompetence with the treating physician or by other means (e.g. appointed expert such as psychologist, psychiatrist);
6. whether incompetence is permanent.

Paragraph 3
In addition to paragraph 2, Authorization given on behalf of an incompetent person should explicitly cover the following elements:

1. the reason why the person is permanently unable to provide Informed Consent on his or her own;
2. the ground for the power of representation of the incompetent person;
3. statement that to the knowledge of the representative no objection to post-mortem donation for research purposes or similar objection has been made by the

incompetent person, prior to becoming incompetent;
4. statement that the person signing Authorization is not aware of any circumstances which would forbid him or her to represent the person or otherwise forbid to sign the Authorization;
5. statement that the person signing Authorization understands that Authorization can be withdrawn at any time. If the incompetent person is a patient it should be specified that withdrawal will not affect the medical treatment in any way.

Clarifications to art. 17

A person's competence to give Informed Consent must be evaluated according to national law and professional guidelines (art. 14 par 3 of the Convention on Biomedicine).

As a guideline: persons with a severe mental disease or other condition, who as a result of that condition are unable (incapable) to understand the information provided in order to make personal decisions, are considered incompetent. Children are also legally incompetent.

Incompetence is not always apparent. The following elements should be taken into consideration when evaluating the degree of competence of the person concerned:

1. *is the information given in a personalized and accessible form, considering that person's capabilities? This means that information should be provided in a manner appropriate to the circumstances.*
2. *is the person able to understand the information given?*
3. *is the person able to make a choice and to communicate his or her wish?*

When the person is regarded incompetent, a representative may take over. It should be established in accordance with national law who exactly has the power of representation. A representative must observe that the personal values of the incompetent person are not violated.

As a guideline it can be said that there are three kinds of representatives:

1. *a representative who has been named by a court of law;*
2. *an appointed representative: where a person (e.g. a friend) has been appointed as a representative by the incompetent person prior to becoming incompetent;*
3. *a representative by law (a parent or a legal guardian when it concerns a child and a spouse or, in the absence of a spouse the closest blood relative when it concerns an adult).*

Article 18 Special considerations when residual Materials are collected

Article 18 Special considerations when residual Materials are collected

<...>

Article 19 Consent documentation

This article instructs the Brain Bank to keep a proper administration of consents.

Article 19 Consent documentation

All Consent and Authorization forms shall be attributed a unique number and appropriately documented including any restrictions placed or any instructions or special requirements imposed by the donor, next of kin or representative.

Article 20 Unconsented Materials and Data

The Draft Guidelines by OECD instruct that in cases where:

- *human biological materials or data are to be used in a manner not anticipated in the original informed consent process;*
- *including for previously collected human biological materials or data where the use might deviate from the original consent;*
- *for cases where informed consent may not have been obtained at the time of collection;*
- *for determining when to seek re-consent; and*
- *for use of human biological materials or data which were consented using a broader or layered format for unspecified future uses, especially in the case of large-scale genetic epidemiology studies,*

review processes including reviews by research ethics committees or other oversight mechanisms, should be in place.

Article 20 Unconsented Materials and Data

In case the Materials or data are to be used in a manner not anticipated in the original Informed Consent process, including for previously collected Materials or data where the use might deviate from the original consent or where informed consent may not have been obtained at the time of collection, the use of such Material and Data shall be

1. reviewed by a research ethics committee [or other oversight organ], whereas [organ/person] will determine whether seeking re-Consent or re-Authorization is justified;
2. Material and data will be Fully-Anonymized.

Article 21 Withdrawals

This article contains a model standard operating procedure in case of consent withdrawal.

Article 21 Withdrawals

Paragraph 1
A request to withdraw a previously given consent or authorization shall be promptly

responded to by the <BB>, taking care to:

1. identify the person and his or her request;
2. explain the consequences of withdrawal and choices in that respect;
3. explain the way the Material and Data shall be disposed of and choices in that respect;
4. inform the person who in the past has given consent or authorization and is now submitting a request for withdrawal that any Material and Data which already have been used for research cannot be recalled and that a record of previously given Authorization or Consent shall be retained.

Paragraph 2
A unique reference number of the withdrawn Consent of Authorization including any particular instructions placed by the donor, next of kin or a representative shall be retained in a withdrawal register. In case the database containing donor or other personal data needs to be reinstated through the use of the Backup Media, all Informed Consents and/or Authorizations documented in the withdrawal register should be updated according to the withdrawal register, before the database is used.

CHAPTER III

With regard to processing and protection of data

Article 22 Data stored at the Brain Bank

Data stored at the Brain Bank is defined in this article.

Not all data needs the same level of protection. When processing data it is advisable to classify data according to their degree of sensitivity. One can let oneself be guided by the principle that any data that can cause damage to the persons concerned upon unauthorized disclosure should always be regarded as sensitive data. Identifying personal data should always be regarded as sensitive data.

For example, in these regulations we have indicated the sensitivity of the data by colour (red requiring the highest level of protection and green indicating the data is not sensitive).

Article 22 Data stored at the Brain Bank

Paragraph 1
Identifying Data stored at the Brain Bank consist of:

a. <Personal Identifying Data of living persons who are registered as a Donor, including clinical diagnosis and additional data>;
b. Identifying data of the next of kin or family member or legal guardians of the prospective or deceased donors;
c. A copy of Identifiable patient records of the deceased donors, obtained from their physicians and care providers;
d. Identifiable neuropathological data of the deceased donors;
e. <Samples of Material with labels containing identifying information>;

Paragraph 2
For the purpose of this Chapter of the Regulations any key for decoding of pseudo-

anonymized data is regarded as identifiable data.

Paragraph 3
Pseudo-anonymized data stored at the <BB> consist of:
a. coded anonymized extractions of the medical records of the donors;
b. samples of Material with coded labels;
c. <other>.

Paragraph 4
For the purpose of these Regulations any other data of a confidential nature shall be treated as confidential.

Article 23 Purposes for which the data is collected

It should be explicitly justified why a certain amount must be collected. Define the purposes carefully.

Article 23 Purposes for which the data is collected

Paragraph 1
Identifiable data of living persons is collected and retained for the purposes of:
a. donor registration and administration;
b. donor tracking.

Paragraph 2(*)
Identifiable data of the deceased persons is collected and retained for:
a. conduct of the autopsy according to national guidelines and laws;
b. feedback of the neuropathological diagnosis;
c. making extractions of medical records to be used in scientific research;
d. case selection on the basis of a certain request;
e. retrieval of the supplementary anonymous information not included in the extraction and requested by scientists.

Paragraph 3
Data shall not be processed further without express Consent or Authorization thereto.

(*)Clarifications to Paragraph 2
Data of deceased persons should be treated according to the principle "confidentiality of medical records goes beyond the grave". Although all personal rights cease to exist at the moment of death, certain obligations stay in force, among them an obligation to maintain confidentiality of medical records, disclosing them only in accordance with consent of the deceased.

Article 24 (Pseudo) anonymized data

Data which can be regarded as pseudo-anonymized and anonymized are defined here.

Article 24 (Pseudo) anonymized data

Paragraph 1

Data and Material can be regarded as pseudo-anonymized when:
the following identifying parameters have been removed:

i. person's name (s),
ii. (most recent) address;
iii. relationship to any living identifiable person (*);
iv. date and place of birth;
v. date and place of death;
vi. identifiable photographs, audio- or video-recordings or any other identifiable images;
vii. any number or code by which a person who is not authorized to receive identifiable data can link data to the identity of the donor or data subject.

all other parameters may be regarded sufficiently generic to prevent identification of the person concerned, in accordance with paragraph 2 of this article

a meaningless number has been attributed to the case.

Paragraph 2
Data and Material should be screened and judged on a case by case basis for the presence of any other possibly identifying parameters or a combination of parameters by which a person can be identified, such as:

1. very old age;
2. rare occupation;
3. rare and publicized disease of an identifiable person;
4. experimental or publicized treatment of identifiable person;
5. unusual or publicized cause of death;
6. any other combination of parameters, which in themselves are not exceptional but in combination make data identifiable.

Paragraph 3
Data and Material treated in accordance with paragraphs 1 and 2 of this article, with all links to any identifying parameter irreversibly destroyed, can be regarded as fully anonymized.

Paragraph 4
The following parameters may not be removed in the process of (pseudo) anonymization of the Material and Data:

i. any restrictions on the use of material and data imposed by the donor, or by his/her representative or the next of kin;
ii. any specific requirements for disposal of the material as indicated by the donor or the next of kin.

Article 25 Data on subject rights

Individuals should be fully informed of the use to which information about them may be put and the extent to which it may be shared. Also see Chapter II (Guidelines on Informed Consent or Authorization). Please note that the rights mentioned in this article concern OWN data only, not data of the deceased relative.

Article 25 Data subject rights

Paragraph 1
Where it concerns processing of personal identifying data, these persons retain the following rights with regard to their personal data:

1. to be informed of the data processing (*);

2. to object to any use of their personal data;
3. to access their data;
4. to take action to rectify inaccuracies and make supplements;
5. to lodge a complaint and/or seek compensation in case of damages suffered by any contravention of personal data rights.

Paragraph 2
When data of a minor or an incompetent person is processed, data subject rights may be exercised by a legal guardian or an appointed representative of that person.

Paragraph 3
<SOP to respond to requests for access to own personal data>.
A request to access, modify or remove (**) personal data should

1. be addressed to the <Head of the Brain Bank>;
2. contain identification of the requestor and recipient;
3. contain a description of the information requested to be accessed/modified or removed;
4. describe grounds for the request for disclosure, such as a reference to act, law, statutory regulation or court order by which the person or organization is entitled to receive such information.

Any decisions regarding disclosure shall be made by the Head of the Brain Bank, if in doubt, after seeking legal advice.

Paragraph 4
<BB> shall keep a list of "withdrawn donor data" that must be stored with the backup medias. When a backup is reinstated, it must be ensured that the list of "withdrawn donor data" is removed from the reinstated data.

(*)Clarifications to Paragraph 1 sub 1
Individuals should be fully informed of the use to which information about them may be put and the extent to which it may be shared. Also see Chapter II (Guidelines on Informed Consent or Authorization).

Please note that the rights mentioned in this article concern OWN data only, not data of the family member or the relative.

(**)Clarifications to Paragraph 2 sub 1 and Paragraph 3
Whenever the request to remove data is granted it is simple to remove the data from the currently running set of data. However, it must be noted that the information cannot be selectively erased/removed from all backup media (this is physically impossible). A Brain Bank must therefore keep a list of "not to be viewed items" that must be stored with the backup medias. Then, whenever a backup is reinstated, it must be ensured that the list of "non viewable items" is removed from the reinstated data.

Article 26 Disclosure of identifying data

This article limits the number of persons and organizations with access to identifying data of the donors. Data should not be disclosed further than the persons and/or organizations named in this article.

Article 26 Disclosure of identifying data

Paragraph 1
Directly identifiable data including medical records of the donors shall only be disclosed to:

i. Employees of the <BB/Legal entity> who are involved in the processing of identifiable data for the purposes mentioned in art. 28 (Authorized Individuals);
ii. Doctors and assistants who perform autopsy and post-mortem diagnostics;
iii. Doctors who have been involved in treatment and care of the deceased;
iv. Undertakers transporting the deceased;
v. Other persons or organizations performing services for the <BB>, in full compliance with paragraph 2 of this article (confidentiality);
vi. Persons or organization to which information is required to be disclosed by law, regulation or an order of a competent authority;
vii. <Relatives, representatives and the next of kin or any other persons – in accordance with consent or instructions of donor, taking care to identify the enquirer>.

Paragraph 2
Any third party providing services to the Brain Bank for which a disclosure of Identifying Data is required shall be required to agree contractually to maintain the confidentiality and security of any identifying data provided to that party.

Paragraph 3(*)
Requests to disclose identifying data from persons and organizations mentioned in paragraph 1 under IV, should be:

1. submitted in writing to the <Head of the Brain Bank>;
2. contain identification of the requestor and recipient;
3. contain a description of information which is requested to be disclosed;
4. describe grounds for request for disclosure, such as a reference to act, law, statutory regulation or court order by which the person or organization is entitled to receive such information.

The Head of the Brain Bank shall take decisions about disclosure, if in doubt, after seeking legal advice.

Paragraph 4
Where a pressing public interest prevails over the duty of confidentiality, the duty of confidentiality can only be overridden

i. by a decision taken on the basis of individual cases if in doubt, after seeking legal advice;
ii. whereas alternative means which do not lead to breach of confidentiality have been sufficiently considered.

The decision should be documented where public interest justification is clearly stated.

Paragraph 5
If the request is approved, only a copy of the requested information and no more shall be provided to the requestor.

(*)Clarifications to Paragraph 3
In situations where disclosures to or information-sharing with the authorities (e.g. police) become routine, a formal protocol should be developed and agreed between the <BB> and the authority, so that all staff involved know how to act.

Article 27 Authorized individuals

Individuals authorized to view and process sensitive data should be specified.

Article 27 Authorized individuals

Paragraph 1
Authorized individuals as mentioned in Article 27 (Responsibilities) are appointed by <organ/person>.

Paragraph 2
Authorized individuals are provided access to identifiable data only for the purposes mentioned in Article 7 (The objectives) of the <BB>.

Paragraph 3 (*)
Authorized Individuals <have signed non-disclosure agreements> or <contracts of employment with Authorized Individuals contain non-disclosure provisions>, including explicit reference to the obligations and the consequences of breaches of confidentiality.

(*) Clarifications to Paragraph 3
Authorized individuals should know what they must do to keep information secure and confidential, and what information they may and may not disclose outside their immediate working environment.

Article 28 Data integrity

Measures to safeguard data integrity should be defined.

Databases or files containing identifying data and other sensitive data should be protected against

- *unauthorized viewing;*
- *unauthorized copying;*
- *unauthorized entries;*
- *unauthorized modification;*
- *unauthorized deletion;*
- *unauthorized disclosure/communication;*
- *accidental loss.*

Article 28 Data integrity

Paragraph 1
Measures to safeguard data integrity should be put in place. These include daily automated backups, and, where possible, media mirroring.

Paragraph 2
Regular backups of all identifying data should be made. All backup media should be fully encrypted and only accessible by password. All backup media must be housed in a secured archive such as a locked safe, preferably outside the Brain Bank.

Paragraph 3 Access Control
Unauthorized Access to Material and Data should be prohibited and measures put in place to ensure Access control.

Paragraph 4 (*)
Physical access control and electronic access control should be implemented and maintained by the following measures:
Appointing an IT Systems Administrator who is responsible for the implementation of the following controls:
Physical access control

1. placing locks, code locks or magnetic cards permitting access only to the holder of the key or a card access to rooms in which any computer processing equipment that processes identifiable data is kept
2. appointing authorized individuals and maintaining their accesses (Systems Administrator);
3. securing computers from theft through wire attachments.
4. implementing and maintaining clear desk policy;
5. implementing and maintaining clear screen policy;

Electronic access control

1. applying self-expiring passwords for access to the computers/network (usually one step);
2. if databases are used, separate self-expiring passwords must be assigned to these databases, to ensure that only authorized individuals have access;
3. anti-virus and anti-spyware software with daily checks and updates;
4. if the Brain Bank is connected to the Internet, a hardware (not software) firewall to ensure network security.
5. when possible, maintaining a local in-built encrypted network, to ensure that access to databases containing directly identifiable data is encrypted.

Paragraph 5 Medium Control
It should be ensured that Removable Data Media (Cds, USB Sticks etc) and Backup Media (CDs, Tapes etc) cannot be read, copied, modified or removed by unauthorized persons.

Paragraph 6
Removable Data Media
Directly Identifiable data should not be stored on Removable Data Media.
Backup Media
If encrypted, password-protected and stored in secure archives Directly Identifiable data can be stored on internal Backup Media.

Paragraph 7
If encrypted and password-protected all other confidential data can be stored on Removable Data Media.

Paragraph 8
Whenever identifying data is processed on laptops, these should be protected with:

1. whenever technically possible (Windows Vista, OSX), the hard disk must be fully encrypted;
2. self-expiring passwords that must be typed in on start-up of the laptop;
3. the laptop must "lock itself" after a maximum of 20 minutes of inactive use, requiring the need to retype the password on "wakeup" of the laptop
4. anti-virus and anti-spyware software, that checks and downloads updates daily must be installed and be in use and the real-time protection feature of the anti-virus software must be switched on.
5. The laptop's make, model and serial number must be registered with your local systems administrator;

Additionally, whenever the laptop must be taken outside the confines of the Brain Bank and identifying data needs to be stored on the laptop:

1. identifiable data should not be stored on a laptop in any permanent fashion whatsoever but only when necessary, in the amount necessary and only for as long as necessary. A laptop secured in the way stated above, that is required to leave the confines of the Brain Bank temporarily, can store identifiable data, but only when this is absolutely necessary for the purpose in question, and even then only for the exact purpose in question and its limited duration. Once that purpose is

fulfilled the identifiable information must again be removed from the laptop. Care is to be taken to only store the information needed for the purpose in question and no more, as well as no longer than necessary. Identifiable data may not be stored on a laptop in a permanent fashion (i.e. you may not use your laptop as a database server for identifiable data or keep exports of your local database with identifiable data on it permanently).
2. If identifiable data is to be taken out of the Brain Bank confines on a laptop, full disk encryption (Vista, OSX, Windows XP separate program) as well as points 1-5 above, are now requirements.

Paragraph 9 Storage Control
Safeguards to avoid unauthorized entry into the memory of the Data Processing Equipment, resulting in unwanted perception, modification or deletion of Identifying Data should be put into place.

Paragraph 10
Storage control should be implemented and managed by:
1. installing anti-virus and anti-spy ware software;
2. applying network monitoring tools;
3. applying measures mentioned in the article on Access Control and Medium Control.

Paragraph 11 External Access Control
Safeguards to avoid the usage of the Data Processing Equipment via Data Communications Equipment by unauthorized persons should be implemented and maintained by
1. installing and operating at least one hardware based firewall and having it configured by qualified personnel;
2. line-height: 115%; font-family: verdana, sans-serif; ">installing anti-virus and anti-spy ware software on all computers with which identifying and confidential data are processed.

Paragraph 12
Directly identifiable data should never be sent across email or internet based voice systems outside the confines of the <BB>.

Paragraph 13
It should be ensured that one can check and retrospectively determine to which destinations Identifying Data has been sent via Data Communications Equipment. Transmission control should be implemented and managed by:
1. self expiring passwords controlling access to computers and databases;
2. system logging.

Paragraph 14
It should be ensured that authorized access to the Data Processing Equipment allows the authorized individual to access only his or her authorized data and no more.

Paragraph 15
Scope of the access control should be implemented and managed by self expiring passwords controlling different levels of access to computers and databases.

Paragraph 16
It should be ensured that one can reproduce and retrospectively determine which data entries were created and modified at what time and by whom, implemented and managed by:
1. self expiring passwords controlling access to computers and databases and
2. system logging.

Paragraph 17
It should be ensured that Identifying Data processed by a person authorized to use the relevant system is processed in the required way to achieve the desired objectives and no more.

Paragraph 18

Measures to prohibit unauthorized reading, copying or modification of Identifying data during the communication of such data via networks or data access media should be in place.

Paragraph 19
The internal organizational structure should be structured and organized in such a way that it is able to comply with all of the above-mentioned data protection requirements.
In order to comply with the requirements of organizational control

1. at least one IT responsible person should be designated;
2. annual auditing of the systems storing identifying data should be performed by the IT responsible person to ensure their continued compliance to these rules.

CHAPTER IV

With regard to distribution of the material

Article 29 Distribution of the Material

In compliance with art. 3. Draft Guidelines by OECD and art. 20 of the Code of Conduct: procedures for review of applications for access to the human biological materials and/or data should be in place.

Article 29 Distribution of the Material

Paragraph 1
All requestors shall be required to fill in an <Application Form>.

Paragraph 2
All requests shall be documented and attended to within a period <of six weeks> starting from the date of receipt of the application form.

Paragraph 3
<Information provided in the process of request for Material shall be treated as confidential and shall only be disclosed to the persons evaluating the request.>

Article 30 Evaluation of requests

Article 30 Evaluation of requests

Paragraph 1
Requests shall be evaluated by <organ/panel>, consisting of individuals knowledgeable in the requestor's field of research and science.

Paragraph 2
Before the contents of the request are evaluated it shall be considered whether the following formal requirements have been satisfied:

a. whether requested Material and Data are available;
b. whether the requestor is an end-user or an agent;
c. whether requested Material and Data are scarce <and the request is in line with the art. 8 Priorities, Chapter I>;

d. whether all fields in the application form have been completed:
e. whether all required approvals by the ethics committee or institute research boards have been obtained.

Paragraph 3
The <organ/panel> evaluating the request shall consider:
i. whether persons evaluating the request are competent to evaluate. If necessary an expert opinion shall be requested;
ii. whether any person should withdraw from the evaluation panel due to a conflict of interest.

Paragraph 4
Evaluation of the contents of research shall take place according to the following criteria:
a. whether the requested Material and Data are suitable for the requestor's research;
b. whether the amount of requested Material and Data is not excessive in relation to the objectives of research;
c. <other>.

Paragraph 5
When selecting Material for a requestor the following must be considered at all times:
a. Is research within the scope of the Informed Consent or Authorization given?;
b. Are there any restrictions on the use of the Material and Data?;
c. Where it concerns Material and Data from incompetent persons, have the criteria specified in article 7 paragraph 3 Code of Conduct been satisfied?;
d. Has Ethical Approval (where applicable) been obtained for the project for which the material is requested?

Article 31 Material Transfer Agreement

Article 31 Material Transfer Agreement

Material on data shall only be transferred to the user on the basis of the material transfer agreement signed by the individual holding authorization to represent the <user/user organization>.

Article 32 Financial contribution

Article 32 Financial contribution

Paragraph 1
The financial contribution from users shall not exceed the total amount of costs of procurement, processing and distribution of the Material and Data.

Paragraph 2
The total amount of financial contribution payable shall be calculated <please specify>.

Article 33 Co-authorship of the employees of the Brain Bank

The policy regarding co-authorship and co-inventorship of the employees should be specified here.

Article 33 Co-authorship of the employees of the Brain Bank

Paragraph 1

Paragraph 2

Paragraph 3

CHAPTER V

With regard to management and governance, including organs, responsible persons, their appointment, tasks and competences

This chapter defines the responsible persons and/or organs, involved in management and governance of the Brain Bank. As the contents of this chapter highly depend on the internal structure of the Brain Bank and its relation with independent institutions, this chapter is provided with examples of the NBB's structure.

Article 34 Organs and Responsible Persons

In compliance with art. 3. Draft Guidelines for Human Biobanks and Genetic Research Databases [1]: 3.B. The initiators of the biobanks should clearly formulate the governance structure and management responsibilities applicable to the biobank and should make this information available to participants, stakeholders and the general public.

It is advisable to describe the decision-making competences, and whether any decision can be overruled by a certain person or organ.

Article 34 Organs and Responsible Persons

The <BB> has the following organs and responsible persons:

1. <Head/management>;
2. <Scientific commission/Request Review panel>;
3. <Advisory council>.

Article 35 <Head/management>

Article 35 Organs and Responsible Persons

Paragraph 1
<Head of the <BB>/Management> is appointed by <…>.

Paragraph 2
The tasks of <Management/Head NBB> include:

i. daily management;

ii. coordination of all Brain Banking activities within the approved budget and mandate;
iii. drafting policies;
iv. drafting annual planning and long-term plans;
v. executing policies approved by <...>;
vi. drafting an annual budgetary estimation;
vii. drafting standard operating procedures, protocols and contracts;
viii. performing other tasks which are required for good management and
ix. ensuring quality standards of the services provided by <..>.

Article 36 <Scientific Committee/Request Review Panel>

Article 36 <Scientific Committee/ Review Panel>

Paragraph 1
<Scientific Commission/Review Panel> consists of <three> persons, appointed by <...>

Paragraph 2
The tasks of the <Scientific committee/Review Panel> include:
i. reviewing all applications for Material and Data;
ii. deciding upon specific conditions of the material transfer;
iii. prioritization in cases of applications for scarce material, in accordance with objectives and priorities as specified in Article 8 Chapter 1 of these Regulations.

Paragraph 3
The <Scientific commission/Review Panel> decides upon requests, taking into account Chapter 4 of these regulations.

Article 37 Oversight

In compliance with art. 3. of OECD Draft Guidelines for Human Biobanks and Genetic Research Databases [1]: 3.F. A biobank should have in place oversight mechanisms to ensure that the governance, management and operation of the biobank comply with applicable domestic and international ethical, financial, and regulatory legislation, policy and frameworks.

According to OECD guidelines: 3.G. In light of the nature and purpose of the biobank the individuals involved in the oversight procedure should be drawn from various relevant areas of expertise, including the scientific, legal, and ethical fields.

Article 37 Oversight <by advice council>

Paragraph 1
Any person eligible to be a member of the <advice council> can be invited by <organ/person>. If accepted, this person is appointed as a member of the advice council for a period of 3-5 years with a possibility of reappointment.

Paragraph 2
The advice council consists of <…> persons, including lay members.

Paragraph 3
The members of the advice council meet at least once a year or when deemed necessary.

Paragraph 4
Advice council has the following tasks:

i. <...>
ii. <...>
iii. <...>

Glossary

This is a glossary of some terms used throughout the Brain Bank Regulations.

Access Control

Access Control measures:

1. Passwords should expire every three months, unless removed from system or prolonged;
2. Accounts should expire every year unless removed from system or prolonged;
3. all computers (desktops, servers and laptops) must be configured to engage a screensaver after a minimum of 20 minutes idle time, and the feature must be configured in such a way that a user must re-enter his password to wake the computer up from sleep.
4. access to databases containing Directly identifiable data by authorized persons should not be made available via the Internet (appropriate Firewall devices may be required)

External Access Control

All computers (desktops, servers and laptops) without exception must be protected by an up to date virus scanner and anti spyware software. Recommendations: F-Secure for PCs, Symantec Anti Virus for PCs and/or Macs. Sufficient licenses should be purchased to allow employees to run one license on their home computer.

Legal personality

Legal personality (or legal entity) means: a legal construction whereby an organization can function as a natural person for legal purposes. An organization which is a legal entity can have possessions, debts, sign contracts and file lawsuits. An organization can only be perceived as a legal entity if it has been established as such according to national law. In most cases the University will be the legal entity acting for and on behalf of the Brain Bank.
Example given: The Netherlands Brain Bank is a department of the Netherlands Institute for Neuroscience, an institute of the Royal Netherlands Academy for Arts and Sciences. The Royal Netherlands Academy for Arts and Sciences is a public legal entity which has its registered seat in Amsterdam and has been established by the Law on Higher Education and Research.

Medium Control

Backup media must be password protected and encrypted and stored in a location outside the Brain Bank, locked safely away, or inside the Brain Bank in a fireproof safe.
Users should be instructed to place their Name, Contact telephone number and address in a text file on any USB Keys, so they may be returned in case of loss.
(Recommendations for Backup Software: less than 50 computers: Retrospect by Dantz for PCs and Macs, more than 50 computers: Veritas Backup Exec).
Laptops should have their model and serial number written down with the <IT> responsible.