



UNIVERSITA' DEGLI STUDI DI SIENA

Biobanking Chair

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Slides set # 2

Guidelines for the certification and accreditation of biobanks

Con il contributo di



The Centre of Transfusion Medicine, Cellular Therapy and Cryobiology (CTMC) operates with several reference quality standards, including:

- ISO 9000 (Vision)
- Netcord/FACT (Foundation for the Accreditation of Cellular Therapy)
- JACIE (Joint Accreditation Committee- I SBT & EBMT)
- GMP (Good Manufacturing Practice)
- GAMP (Good Automated Manufacturing Practice)
- OECD Best Practice Guidelines for BRC

Biobanking guidelines

- An international example (OECD)
- A national example (Italy)

Organization for the Economic Cooperation and Development
OECD
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OCSE

- The OECD is a unique forum where the governments of **30 democracies** work together to address the **economic, social and environmental challenges of globalisation**. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.
- The OECD **member countries** are: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, **Italy**, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States.
- The **Commission of the European Communities** takes part in the work of the OECD.
- **OECD Publishing** disseminates widely the results of the Organisation's statistics gathering and research on economic, social and environmental issues, as well as the conventions, guidelines and standards agreed by its members.

Source: OECD

OECD Guidelines on Human Biobanks and Genetic Research Databases - 2009

This Recommendation is **not** intended to exhaustively **cover all aspects** of HBGRDs.

For example, the OECD ***Recommendation on Quality Assurance in Molecular Genetic Testing***, adopted by the OECD Council in 2007, sets out, *inter alia*, a number of principles and best practices for governments, professional bodies and providers of molecular genetic testing services.

The OECD ***Recommendation on the Licensing of Genetic Inventions***, adopted by the OECD Council in 2006, provides guidance on licensing, transferring agreements and joint development activities in regards to genetic inventions.

The OECD ***Best Practice Guidelines for Biological Resource Centres*** set out further complementary quality assurance and technical aspects for the acquisition, maintenance and provision of high-quality biological materials in a secure manner.

OECD Guidelines on Human Biobanks and Genetic Research Databases - 2009

Nature of the document

This *Recommendation on Human Biobanks and Genetic Research Databases* was adopted by the OECD Council on **22 October 2009**.

This Recommendation, and the Guidelines (“Guidelines”) that it sets out, are intended to be **evolutionary** in nature and should be reviewed in light of relevant scientific and societal developments.

Thus, there will be a need for the Recommendation and its Guidelines **to be assessed, five years after adoption** at the latest, and periodically thereafter, in order to ensure that it is fostering the desired objectives.

While a Recommendation of the OECD Council is a non-legally binding instrument, it represents an **important political commitment** on the part of the member countries.

Source: OECD

OECD Guidelines on Human Biobanks and Genetic Research Databases - 2009

Part I.

➔ Guidelines on Human Biobanks and Genetic Research Databases

1. General elements
2. Establishment of HBGRDs
3. Governance, management, and oversight
4. Terms of participation
5. Contents of HBGRDs
6. Protection of human biological materials and data
7. Access
8. Qualifications, education and training
9. Custodianship, benefit sharing and intellectual property
10. Discontinuation of the HBGRD and disposal of materials and data

OECD Guidelines on Human Biobanks and Genetic Research Databases - 2009

1. General elements

Principles

- 1.A The objective of an HBGRD should be **to foster research**.
- 1.B HBGRDs should be established, governed, managed, operated, accessed, used and discontinued in accordance with applicable **legal frameworks and ethical principles**.
- 1.C The operators of the HBGRD should strive to make **data and materials rapidly and widely available** to researchers so as to advance knowledge and understanding.
- 1.D Throughout its existence, the operators and users of the HBGRD should **respect human rights and freedoms** and secure the protection of participants' privacy and the confidentiality of data and information.
- 1.E The operators of the HBGRD should consider and **minimise risks to participants, their families and potentially identifiable populations or groups** whose specimens and data are included in the HBGRD.
- 1.F The operators of the HBGRD should develop and maintain **clearly documented operating procedures and policies** for the procurement, collection, labelling, registration, processing, storage, tracking, retrieval, transfer, use and destruction of human biological materials, data and/or information.
- 1.G The operators of the HBGRD should be explicit and transparent about the nature and source of its **financing/funding**.
- 1.H The operators of the HBGRD should ensure that aggregate and general results of research conducted using its resources, regardless of outcome, are made **publicly available** either in the form of publications or through other means.

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2. Establishment of HBGRDs

Principles

- 2.A The **purpose**, both current and for the foreseeable future, of the HBGRD should be clearly formulated and communicated.
- 2.B The operators of the HBGRD should ensure that **sufficient professional staff and resources** are available to operate effectively.
- 2.C The operators of the HBGRD should develop a strategy for ensuring its **long term sustainability**, which also addresses the event that funding is terminated or its nature changed.
- 2.D In the establishment of a new HBGRD, the operators should consider which **relevant stakeholders**, including the general public, should be consulted.

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3. Governance, management, and oversight

Principles

- 3.A The HBGRD should be governed by the principles of **transparency and accountability**.
- 3.B The operators of the HBGRD should clearly formulate its **governance structure and the responsibilities** of its management and should make such information publicly available.
- 3.C The governance structure should be designed to ensure that the **rights and well-being of the participants prevail over the research interests** of the operators and users of the HBGRD.
- 3.D The operators of the HBGRD should have in place **oversight mechanisms** to ensure that the governance, management, operation, access to, use of and discontinuation of the HBGRD **comply with legal requirements and ethical principles**.

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4. Terms of participation

Principles

- 4.A Participant recruitment should be carried out in a non-coercive and equitable manner that respects **individual freedom of choice**.
- 4.B **Prior, free and informed consent** should be obtained from each participant. The HBGRD may provide for obtaining consent/authorisation from an appropriate substitute decision-maker, or for obtaining waiver of consent from a research ethics committee or an appropriate authority, in accordance with applicable law and ethical principles pertaining to the protection of human subjects.
- 4.C The operators of the HBGRD should give careful consideration to any special issues related to the participation of **vulnerable populations or groups**, and their involvement should be subject to protective conditions in accordance with applicable law and ethical principles.
- 4.D The operators of the HBGRD should have a clearly articulated policy on whether participants may be re-contacted during the course of the HBGRD's existence, the situations for which re-contact will be permitted, and the **conditions that will govern re-contact**.
- 4.E The operators of the HBGRD should disclose to participants, insofar as possible, the exceptional conditions under which researchers may be provided **access to human biological materials or data that is not coded or anonymised**.

Source: OECD

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4. Terms of participation (cont'd)

Principles

- 4.F Participants should be provided with explicit information on whether and under what circumstances the **operators of the HBGRD may be obliged legally** to provide their human biological materials and data, in whole or in part, to third parties (e.g. law enforcement agencies, employers, insurance providers) for non-research purposes.
- 4.G The operators of the HBGRD should inform participants of their **right to withdraw**, of the nature of and modalities for exercising that right, as well as the implications of and limits to exercising that right.
- 4.H The operators of the HBGRD should provide participants with information about **commercial products** that may arise from research conducted using its resources, including human biological materials, data derived from the analysis of samples, data or other information provided by or about the participant. Information should also be provided on the benefits, if any, the participant may receive.

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5. Contents of HBGRDs Principles

- 5.A Throughout the existence of the HBGRD, the operators should ensure that the **collection and use** of participants' human biological materials and data are **scientifically, legally and ethically appropriate**.
- 5.B The operators of the HBGRD should have a **clearly articulated policy of whether data will be accessed from health or other records**, and/or be independently assembled, and whether or not these data will be linked with or stored in the HBGRD.
- 5.C The operators of HBGRDs releasing human biological materials and/or data should have a clearly articulated policy on whether and how the **results** of research and analyses carried out using its resources should be **returned to the HBGRD**, incorporated into its databases and how access to such results for further research will be managed.

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5. Contents of HBGRDs (cont'd) Principles

- 5.D All human biological materials and data within the HBGRD should be subject to **proper quality control measures** at every stage of processing to ensure high standards of quality.
- 5.E To foster the interoperability of systems and facilitate the scientific exchange of data and human biological materials, the operators of the HBGRD should strive to collect, process, handle and store human biological materials and data in a manner consistent with **internationally accepted technological standards and norms**.

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6. Protection of human biological materials and data

Principles

- 6.A** The HBGRD should be established, managed, governed, and operated in such a way as to **prevent inappropriate or unauthorised access** to or use of participants' human biological materials and personal data and/or information.
- 6.B** The operators of the HBGRD should establish and implement specified policies and procedures for the **protection of human biological materials and data**, especially those potentially permitting, whether directly or indirectly, the identification of the participant.
- 6.C** Prior to the collection of human biological materials or data, the operators of the HBGRD should make available to **participants information about how their materials and data will be protected**.
- 6.D** The operators of the HBGRD should have a clearly articulated policy on the **duration of storage** of human biological materials and data.
- 6.E** The collection, processing, handling, storage, transfer and destruction of human biological materials and data should be conducted in a manner that protects the **privacy** of the participants and the confidentiality of their specimens and data.

Source: OECD

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7. Access

Principles

- 7.A Access to human biological materials and data should be based on **objective and clearly articulated criteria**, and should be consistent with the participants' informed consent.
- 7.B The operators of the HBGRD should require that **access requests include a scientifically and ethically appropriate research plan**.
- 7.C Human biological materials and data should only be transferred when the **recipient has adequate standards in place regarding privacy and confidentiality**.
- 7.D Researchers should only have access to human biological materials or **data that are coded or anonymised**, such that the participant cannot be identified, and researchers should be required to not attempt to re-identify participants. However, under exceptional conditions, researchers may be provided with access to human biological materials or data that are not coded or anonymised.
- 7.E Given the potentially finite nature of some human biological materials, the operators of the HBGRD should formulate criteria for **prioritising applications** for access to the human biological materials.
- 7.F **Except when required by law**, the operators of HBGRD should not make accessible or disclose participants' human biological materials or data to third parties (e.g. law enforcement agencies, employers, insurance providers) for non-research purposes.

Source: OECD

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8. Qualifications, education and training

Principles

- 8.A** The **management** of the HBGRD should have the qualifications, training and experience requisite to carry out the HBGRD's mandate.
- 8.B** The operators of the HBGRD should employ **professional and technical staff** with the appropriate competency to carry out their duties effectively and safely.
- 8.C** The operators of the HBGRD should ensure that all of its personnel are **knowledgeable about its goals and purpose and are made aware of their duties to protect the privacy of participants** and the confidentiality of data and human biological materials.
- 8.D** The operators of the HBGRD should ensure that any **conflict of interest** involving its personnel are disclosed and suitably managed.

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9. Custodianship, benefit sharing and intellectual property

Principles

- 9.A The operators of the HBGRD should **encourage appropriate access** to and use of human biological materials, data, and information with a view to sharing benefits which may include, as applicable, building resource capacity or expertise including in non-OECD members.
- 9.B Benefits arising from research using the HBGRD's resources should be shared as broadly as possible, including by the **sharing of information, licensing, or transferring of technology or materials**.
- 9.C The operators of the HBGRD should have a clearly articulated policy and explicitly indicate to participants **whether they and/or the HBGRD retain any rights** over the human biological materials and/or data and the nature of such rights.
- 9.D The operators of the HBGRD should have a clearly articulated policy that is communicated to participants relating to the **commercialisation** of its own resources, research results derived from those resources, and/or commercial products, if any, that may arise from research using its resources.
- 9.E The operators of the HBGRD should have a clearly articulated policy in regards to **intellectual property** rights, which should address the rights, if any, of the HBGRD, researchers and participants.

Source: OECD

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10. Discontinuation of the HBGRD and disposal of materials and data Principles

- 10.A** The operators of the HBGRD should plan for its possible **discontinuation** and should have a suitably detailed policy setting out the manner in which the human biological materials and data that it holds will be dealt with in the event of its discontinuation.
- 10.B** Where an HBGRD of scientific value can no longer be supported by its current operators, efforts should be made to **transfer** the human biological materials and data **to another HBGRD or another entity**.
- 10.C** Once an HBGRD is no longer required or is no longer of scientific value and it has been determined that it will be discontinued, the human biological materials should be **disposed of in an appropriate manner**, consistent with the principles of consent, privacy and confidentiality.

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Part II.

→ Annotations

1. General elements
2. Establishment of HBGRDs
3. Governance, management, and oversight
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→ Glossary

Source: OECD

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Selected Annotations

2. For the purpose of this Recommendation, HBGRDs are considered to be structured resources that can be used for the purpose of genetic research, and which include: **a) human biological materials and/or information generated from their analysis; and b) extensive associated information.**
5. Examples of different models of HBGRDs for whom this guidance may be useful include: **large-scale collections of human biological material representative of a population or part of a population; epidemiological collections; collections of carriers of specific genetic mutations/markers/ profiles; and collections of samples and data from individuals with a certain disease or taking specific medications.** The resources of an HBGRD may be used for a variety of research purposes to advance our understanding of human health and the life sciences, including in emerging “omics” fields (*e.g.* **proteomics, transcriptomics, metabolomics, cytomics, and microbiomics**).

Source: OECD

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10. Research pertaining to a large portion of a population, especially amongst those sharing common characteristics, may raise issues of **potential discrimination and stigmatisation**. For example, an association between a specific heritage and a particular disease may lead to discrimination from insurers or employers....

15. The initiators and operators of the HBGRD should develop a **business plan** and strategy which should take into account and set out the economic, financial and scientific feasibility and viability of the HBGRD. The business plan should set out the goals, how they will be achieved and the manner in which the HBGRD will be operated. A business plan will draw on different disciplines including: **scientific expertise, finance/accounting, human resource management, and operations management**. It should set out the assumptions and risks inherent to the establishment of the HBGRD. The business plan should also include consideration of the **procedures essential for safekeeping all confidential information** including personal and genetic data.

Source: OECD

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26. The fundamental precept of **prior, free and informed consent** forms the basis for the involvement of human subjects in medical and scientific research. This principle is recognised in international legal instruments, including those applicable in international public or human rights law. Examples of some international legal instruments that make reference to informed consent include:

- **UNESCO *Universal Declaration on Bioethics and Human Rights* (2005),**
- **UNESCO *Universal Declaration on the Human Genome and Human Rights* (1997),**
- ***Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects* (1964, last revised 2008).**

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29. The purpose of the informed consent process is to ensure that potential participants are **able to make a voluntary decision about whether to participate, based on the provision of relevant information.** Within certain cultures, however, it is more common that decisions are considered at the **community or group level** rather than at the individual level. An HBGRD involving different cultural groups should take into account the different approaches to decision-making. This may involve, for example, additional discussions with the community. While researchers should be cognizant of the importance of involving the community or group, as appropriate, they must be **respectful of the need to obtain individual consent.**

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35. The informed consent process should provide information to the potential participant in a **simple and easily understandable manner** and on a variety of subjects. Depending on the nature of the HBGRD, this may include:

- The **purpose** of the HBGRD and **foreseeable risks and benefits** of taking part.
- The **types of human biological materials** and data that will be collected at enrolment and afterwards at subsequent follow-up points, which may include data that some participants consider especially sensitive (with options to avoid certain questions and measurements), and may be linked to health and other records.
- Where applicable, the fact that the **HBGRD will be the legal custodian** of the human biological materials, data, and the collection, and that the **participant may not retain all rights in these**.
- The **intended uses** of the human biological materials and data.
- The general procedures and safeguards used to protect **privacy and confidentiality**.
- The policy with respect to **benefit sharing**.

Source: OECD

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(cont'd)

- Where applicable, the expectation that **commercial entities may be granted access** to the human biological materials, data and information contained within the HBGRD's database(s).
- The policy and means for **ongoing communication with participants**.
- **Information for contacting** the HBGRD.
- The policy with regards to sharing human biological materials and data for non-research purpose with third parties such as insurers, employers or law enforcement agencies or for public health emergencies.
- The policy in regards to **feedback of results to participants**.
- The policy with respect to **re-contact** and the purposes for which such re-contact will be undertaken.
- The policy applicable to the **use** of human biological materials and data of a participant in the event that they become incapacitated or die.

Source: OECD

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(cont'd)

- The storage and **period of storage** of the human biological materials and data.
- Their **right to withdraw**, the nature and modalities of this right and how to exercise this right, including options for dealing with any samples and non-anonymised data, that were given away to third parties (especially, but not limited to, researchers). Participants should be informed that the exercise of the right to withdraw **will not entail consequences in regards to the provision of medical care services.**
- The policy in regards to **intellectual property.**
- The policy on the **commercialisation** of its resources; on commercial products, if any; the modalities of such commercialisation; and the benefits, if any, the participant may receive.

Source: OECD

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53. Different cultural and religious groups may have different attitudes towards biological material, and these may change over time. HBGRDs should take these into account, where they are known, and consider whether any steps should be taken to ensure such views are respected. **Some groups regard certain types of biological material as having a special status, particularly where it is removed post mortem, and as deserving of special treatment e.g. in terms of the method of its handling.** Although this is most likely to be addressed during the consent process, there may be circumstances where this is not the case (e.g. in the case of existing collections).

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58. **Honest broker systems** involve independent third parties who are responsible for ensuring the separation of identifying information from other data. An honest broker may be, for example, a data protection authority. Data enclaves involve the use of a secure or controlled access environment, including databases, servers, networks or websites. They allow the HBGRD or a third party to physically and electronically control and monitor the use of the HBGRD's database(s) by external users to ensure it complies with the terms of access and is in conformity with the participant's consent.

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62. The HBGRD should provide to researchers human biological materials and data that are **coded or anonymised**. However, in exceptional circumstances, **it may be in the participant's interest that the researcher has access to non-coded or non-anonymised materials or data**. For example, this may be the case for research involving rare diseases.

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66. Depending on the nature of the resource, the data/sample provider and the end user, **access agreements** (including data access and material transfer agreements) may address some or all of the following:

- **What is to be provided** (specification of data and materials, format and timing of release);
- **What the data and materials provided can be used for** (this is often limited to a specific project), and what they can't be used for (this may be everything other than the specified project, or something more specific, *e.g.* data linkage);
- The **credentials of the end user**;
- **Fees (or royalties)** payable;
- Arrangements concerning **intellectual property rights** (*e.g.* whether or not IP rights are asserted by the provider over existing or future IP, or any licences sought by them to future IPR);

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- Requirement to **return research findings** to the resource owner to enrich the resource;
- **Requirement to publish** research findings and/or to disseminate them more generally, **and to acknowledge** the resource in publications;
- Requirement to **act in accordance with participants' consent**, and any procedures in the event of withdrawal of consent;
- Requirement to **act in accordance with relevant legal and regulatory requirements**, and obtain ethical approval (where applicable);
- Requirement to **preserve confidentiality, and/or maintain anonymisation** (and not attempt to re-identify or re-contact participants);
- **Limits on** (prohibition of or additional safeguards required for) **transfer of data or materials** to third parties, **including crossborder**;
- **Limits on** (prohibition of) **certain uses** of materials or data;
- **Disclaimers of responsibility** for data/ sample quality;
- **Return or disposal of residual samples** at the end of a project;
- **Termination** (e.g. for default)

Source: OECD

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87. Different cultural and religious groups may have different attitudes to biological material, which can change over time. Some groups may regard certain types of biological material as having a special status and as deserving of special treatment, *e.g.* in terms of the method of its disposal. **Although this is most likely to be addressed during the consent process, it will also be an important consideration at the point of disposal of the human biological materials.** The HBGRD should take these into account, where they are known, and consider how to respect those views. For example, some cultural or religious groups may follow **traditional practices** in the disposal or destruction of human biological materials.

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Glossary (1)

Anonymised/anonymisation. Anonymised data and samples are **initially single or double coded but** where the link between the subjects' identifiers and the **unique code(s) is subsequently deleted.** Once the link has been deleted it is no longer possible to trace the data and samples back to individual subjects through the coding key(s). Anonymisation is intended to prevent subject re-identification. As anonymised samples and associated data are not traceable back to the subject, it is not possible to undertake actions such as **sample withdrawal**, or the **return of individual results**, even at the subject's request. **The use of anonymised data and samples does not allow for clinical monitoring, subject follow-up or the addition of new data from the subject.** The deletion of the coding key(s) linking the data and samples to a given subject's identifiers provides additional confidentiality and privacy protection over coded data and samples, as it prevents subject re-identification through the use of the coding key(s).

Source: OECD

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Assent. This term is used in the context of a **child** participant in research. Even though a child may not be considered legally competent to consent to participate in research, the child may be considered competent to give his/her assent, that is – his/her opinion on whether he/she wishes to participate in the research.

Associated information. Personal, clinical, biochemical and phenotypic information about the participant.

Coded. Where data and samples are **labelled** with at least one specific code and do not carry any personal identifiers.

End user. A health care practitioner, scientist, or laboratory personnel who performs an appropriate procedure, test or archival function for the specimen.

Source: OECD

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Governance. The processes and structures that an entity uses to **set its objectives/goals, appoint the management** whose responsibility it is to achieve these goals and to **oversee management** in its pursuit of these goals.

Governance mechanisms are also needed to put in place internal controls and risk management systems. Management is accountable to the governance bodies that in turn are usually/should be accountable to those who have appointed them.

Human biological material. Includes **specimens, samples and aliquots** of the original material, **and their fractionated components.**

Identifying information. Information that may lead to the identification of the participant from whom the human biological material, data and associated information are obtained.

Informed consent. A process by which **information** concerning the intended research is provided to the participant or participant's substitute decisionmaker with an opportunity for them to **ask questions**, after which specific **approval is documented.**

Source: OECD

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Management. Comprises directing and controlling a group of one or more people for the purpose of co-ordinating and harmonising that group towards accomplishing a goal. Management often encompasses the deployment of human resources, as well as financial, technological and natural resources. Management is responsible for achieving the objectives/goals set for the organisation and is given considerable leeway to undertake this task. While this may be operationally efficient, **there is a possibility that management might act only in their own interests**, hence the need for governance mechanisms.

Material transfer agreement. Generally signed between a provider and a recipient, is used to document the transfer of materials, with or without information, either to an entity (*i.e.* the recipient) and/or away from an entity (*i.e.* the provider) subject to a number of **terms and conditions**.

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Operators. The **researchers, governmental entities and/or organisations** involved in setting up and operating the HBGRD, and including the initiators of the HBGRD.

Oversight is based on the notion that there is usually a **difference** between setting policy and objectives for an entity and overseeing or monitoring how these are being executed or put into operation.

Participant. Individual from whom biological materials, data and information are obtained.

Private entity. May cover **for-profit** entities but may also cover legal entities **not publicly held or traded**.

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Private-public partnership (PPP). A co-operative venture between the public and private sectors, built on the expertise of each partner and involves the allocation of **resources, risks and rewards.**

Processing. Includes **procurement, collection, labelling, registration, storage, tracking, retrieval, transfer, use and destruction**

Research Ethics Committee (REC). A **local authority** that evaluates research projects involving human beings, including genetic research. The primary function of a REC is to **protect the welfare and rights of human participants in research.** Depending on the jurisdiction, these may also be referred to as Ethics Review Board (ERB) or Institutional Review Board (IRB).

Sample. A **single unit** containing material derived from one specimen.

Specimen. A **specific tissue, blood sample, urine sample, etc., obtained from a single participant at a specific time.**

Source: OECD

Linee guida per la certificazione e l'accreditamento delle biobanche

- Documento preparato da una commissione di esperti coordinata dal Comitato per la Biosicurezza, le Biotecnologie e le Scienze della Vita
- Approvato nel 2006
 - Linee Guida
 - Allegati



Presidenza del Consiglio dei Ministri

Comitato Nazionale per la Biosicurezza e le Biotecnologie

**LINEE GUIDA
PER LA CERTIFICAZIONE DELLE BIOBANCHE**

Rapporto del Gruppo di lavoro
19 Aprile 2006

Presidente
Prof. Leonardo Santi

Coordinatore
Dr. Paolo Rebutta



Presidenza del Consiglio dei Ministri

Comitato Nazionale per la Biosicurezza e le Biotecnologie

**LINEE GUIDA
PER LA CERTIFICAZIONE DELLE BIOBANCHE**

ALLEGATI

19 Aprile 2006

Presidente
Prof. Leonardo Santi

Coordinatore
Dr. Paolo Rebutta

Componenti Gruppo di lavoro:

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Il Consenso Informato



Presidenza del Consiglio dei Ministri

Comitato Nazionale di Bioetica

**Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze
della Vita**

**RACCOLTA DI CAMPIONI BIOLOGICI A FINI DI RICERCA:
CONSENSO INFORMATO**

16/2/2009

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Per la struttura di supporto

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Minimum data set
Biobanche di popolazione

Set minimo di dati biobanche di popolazione

Il set è una lista non obbligatoria del tipo di dati che il responsabile della biobanca deve completare se ritiene che siano rilevanti. Il responsabile può aggiungere od aggiornare dati nel registro centrale ogni volta che lo ritenga necessario.

a) dati relativi al soggetto	Obbligatorio	Codifica
- codice Biobanca	Sì	automatico, fornito dal sistema
- Tipo di raccolta	Sì	Codificato: popolazione, disease-oriented
- Tipo di soggetto	Sì	Codificato: singolo, famiglia
- codice del paziente (rigenerato)	Sì	
Campione biologico	NO	Elenco: sangue intero, siero, plasma, buffy coat, emazie, saliva, urine, tessuto, altro (specificare)
- anno di nascita	Sì	Valore intero
- anno del primo contatto	Sì	Valore intero
- sesso	Sì	Codificato: M;F
- diagnosi malattia	Sì	Codificato: ICD9, ICD10
- storia clinica (patologie concomitanti e/o tumori secondari)	No	Tipo Codifica e patologia. (Esempio : ICD9;123.5;ICD10;235.9) oppure descrittivo
- Disponibilità di dati clinici. Demografici, storia familiare patologie concomitanti e terapie	Sì	Codificato: Sì, No
- stato paziente	Sì	Codificato: Vivo, deceduto, dato non disponibile
- data trasmissione	Sì	Codificato: automatico, fornito dal sistema

b) dati sul campione

- data di raccolta del campione	Si	Aaaa/mm/gg
- Materiale	Si	Codificato: Tessuto, Cellule, Cellule da sangue buffy coat; PBMC; Siero; Plasma; Urine:RNA:DNA: saliva, altro (specificare)
- Conservazione	Si	Codificato: Congelato, Crioconservato, paillettes, FFPE, NA
- temperatura	Si	Codificato: temperatura ambiente non controllata Temperatura ambiente $\leq 25^{\circ}\text{C}$, Frigo $+2$ - $+8^{\circ}\text{C}$, Freezer -20°C , Freezer -25 / -40°C , Freezer -80°C freezer -130°C , Azoto liquido fase gassosa, azoto liquido fase liquida.
- Unità di misura	Si	Codificato: Provetta; sezioni; blocchetti;
Quantità	Si	(Numero) Codificato: 1, 2 4, 5 7, ≥ 8

d) Uso

- Tipo di utilizzo	Si	Codificato: Ampio e senza restrizioni/ Ristretto a certe tipologie di progetti / Solo su collaborazione / Non disponibile
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** i mesi interessanti per neonati da 0 a 11 mesi e campioni diversi nello stesso anno

Minimum data set
Biobanche di patologia

Dati minimi per le reti delle biobanche di patologia

Il set è una lista non obbligatoria del tipo di dati che il responsabile della biobanca deve completare se ritiene che siano rilevanti. Il responsabile può aggiungere ed aggiornare dati nel registro centrale ogni volta che lo ritenga necessario.

Reperto

dati del sistema	Obbligatorio	Codifica
- codice Biobanca	Si	automatico, fornito dal sistema
- data trasmissione	Si	Codificato: automatico, fornito dal sistema

Dati da spedire

	Card.	Obbligatorio	Codifica
a) dati relativi al paziente			
- Tipo di soggetto	1	Si	Codificato: tumorale, non tumorale
- codice locale del paziente	1	Si	Testo libero
- Tipo codifica diagnosi istopatologica	1	Si	Codificato ICD9, ICD10, ICDO-2, ICDO-3, NA
- diagnosi istopatologica codice, secondo tipo codifica	1	Si	Codificato: codifica relativa al campo precedente
Tessuto/organo	1	Si	Elenco: Aspirato sternale, Cervice, Colon-retto, Cistifelca, Endometrio, Esofago, Faringe, Fegato, Gastrico, Linfoma, Linfonodo, Mammario, Midollo osseo, Milza, Ovario, Pancreas, Pelle, Peritoneo, Peritoneo, Polmone, Prostata, Rene, Osso, Sangue, Surrene, Testa e collo, Testicolo, Tiroide, Tonsille, Vescica, Vaginale, Altro
Tessuto/organo; specificare ALTRO	1	No	Testo libero se Tessuto/organo è altro
- Stadio TNM	1	No	Codificato TNM
- Stadio codice (non TNM)	1	No	Testo libero

- Stadio valore (non TNM)	1	No	Testo libero
- Grado	1	Sì	Codificato da 1 a 9
- età (al prelievo) anni	1	Sì	Valore intero positive incluso lo zero
- età (al prelievo) mesi	1	No	Valore intero tra 0 e 11**
- sesso	1	Sì	Codificato: m;f
storia clinica (patologie concomitanti e/o tumori secondari)	n		
- Tipo codifica diagnosi		No	Codificato ICD0-2, ICDO-3, IDC9, ICD10, NA
- diagnosi codice, secondo tipo codifica		No	Codificato: codifica relativa al campo precedente o testo libero se NA
- trattamento	1	Sì	Codificato: sì, no
- Disponibilità di dati clinici. Demografici, storia familiare patologie concomitanti e terapie	1	Sì	Codificato: sì, no
- stato paziente	1	Sì	Codificato: vivo, deceduto, NA

b) dati sul campione

- data di raccolta del materiale	1	Sì	Formato: AAAA-MM-GG
- codice locale del campione	1	Sì	Testo libero
Tessuto/organo	1	Sì	Elenco: Aspirato sternale, Cervice, Colon-retto, Cistifellea, Endometrio, Esofageo, Faringe, Fegato, Gastrico, Linfoma, Linfonodo, Mammario, Midollo osseo, Milza, Ovario, Pancreas, Pelle, Penieno, Peritoneo, Polmone, Prostata, Rene, Osso, Sangue, Surreno, Testa e collo, Testicolo, Tiroide, Tonsille, Vescica, Vaginale, Altro
- Tessuto/organo; specificare ALTRO	1	No	Testo libero se Tessuto/organo è altro
- condizione del tessuto	1	Sì	Codificato: tumorale, non-tumorale; interfaccia

Topografia	1		
- Tipo codifica diagnosi istopatologica		Sì	Codificato: ICD9, ICD10, ICDO-2, ICDO-3, NA
- diagnosi istopatologica con ICD9/ICD10/ICDO		Sì	Codificato: codifica relativa al campo precedente o testo libero se NA
- Stadio codifica	1	No	Valore codificato: TNM, altro
- Stadio codice	1	No	Testo libero se Stadio codifica è altro
- Grado	1	No	Codificato: da 1 a 9
- tempo tra l'escissione e il trattamento	1	Sì	Formato: hh:mm:ss
- Presenza di conservanti	1	Sì	Codificato: sì;no;NA

c) campione (vanno previste le compatibilità tra le prime tre colonne)

- Materiale	1	Sì	Codificato: Tessuto, Linfonodo, Cellule, Cellule da sangue buffy coat; PBMC; Siero; Plasma; Urine;RNA;DNA; liquido cefalo-rachidiano; liquido ascitico; altro
- Materiale altro	1	No	Testo libero se materiale altro
- Conservazione	1	Sì	Codificato: Congelato, Crioconservato, FFPE, NA
- temperatura	1	Sì	Codificato: temperatura ambiente non controllata, temperatura ambiente $\leq 25^{\circ}\text{C}$, frigo $+2\text{-}+8^{\circ}\text{C}$, freezer -20°C , freezer $-25\text{-}40^{\circ}\text{C}$, freezer -80°C , freezer -130°C , azoto liquido fase gassosa, azoto liquido fase liquida.
- Unità di misura	1	Sì	Codificato: provetta; sezioni; blocchetti; altro
- Unità di misura altro	1	No	Testo libero se unità di misura altro
- Quantità	1	Sì	Intero positivo

d) Uso

- Tipo di utilizzo	1	Sì	****Codificato: 1,2,3,4
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**** Codificato: 1=Ampio e senza restrizioni; 2=Ristretto a certe tipologie di progetti; 3=Solo su collaborazione; 4=Non disponibile
 ## i mesi interessanti per neonati da 0 a 11 mesi e campioni diversi nello stesso anno
 ICD: necessita di almeno 25 digit

Come avviene la certificazione/accreditamento?

- Visite ispettive (SOP & operations)
- Check list
- Report
 - Non conformità (must/shall)
 - Deviazioni (may/should)
- Risposta: approvato/non approvato
- ➔ **Certificazione**: rispetto dello standard
- ➔ **Accreditamento**: riconoscimento da parte di enti/organizzazioni