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Bio-banks or bio-libraries are public or private institutions engaged in long-term preservation of human biological material and donors' personal data

There are some characteristics that can be used to characterize different types of biobanks. These are size, research design, the types of biological samples collected, the method of sample collection, processing and storage, and the disease/research focus.

The law 196/03 stipulates the principles that must apply to the protection of personal data, given the processing of personal data in biobanks-based research, which can involve sensitive data, such as health and genetic information, socio-demographic data, life style and behavioural data.

The Italian Authority for the Protection of Personal Data, from 2002 to 2014, has published different indication (called "autorizzazioni") to use genetic data and biological samples. In the case of biobank-based research, the indications have highlighted that the data protection regulatory model with its major principles (e.g. fairness, lawfulness, transparency, necessity, security, etc.) must be applied not only to the processing of personal data, but also to the biological samples used for research purposes.

From 2004, the Independent Ethics Committee of Federico II University, Naples, Italy, focused on the issue of uses of human tissue samples for research purposes.

Italy hasn't a law regarding the use of biobanks ad hoc for research purposes; there is only Minister Decree of June, 26th 2006, that consider the biobank like a center for biological research.

In Italy, the laws that have been applied to biobanks have largely been drawn from the legal traditions and jurisprudence that have been developing around the protection of human rights and the advancement of public health

The Federico II Ethics committee has proposed a flow chart, following the various literature indication about biobanks*

1- Organisation and activities

- Identification of adequate structure for biobank;
- identification of specific individual/entity, usually from the medical (or biological) profession;
- identification of suitable security measures to protect biological samples ((Standard Operative Procedure)
 - *quality management system*;
- Collect sample following the research project;
- Use *tracking system* ;
- Respect of *biosafety, packaging e shipping International indication*;
- Sharing the information among researchers
- Use adequately the *Material Transfer Agreements*;
- research ethics committees should assess the purposes to be achieved by setting up the given biobank;
- to create a scientific committee to organize the biobanks activities;
- ad-hoc safeguards are envisaged in some cases to ensure that data and samples are pseudonymised under stringent confidentiality rules (e.g. double code) and the cases are specified in which it may prove necessary to de-code (de-crypt) the information in question.

4. Information and communication to all stakeholders

- Guarantees can protect interests of the community biobanks' accreditation should be sought with the competent national authorities
- supervision should be carried out by the competent national authorities alongside the supervision by the national data protection authority

2. MANAGEMENT of biobank information

To provide supporting measures organize to guarantee the security about

3. Guarantees for individuals

- **informed consent** to donation for research purposes and about the research
 - the patient's consent informative format will be written in accordance with Italian law and approved by Ethics committee
 - clarify the decision-making processes and players involved (The informing and consent of donors must therefore be structured in such a way that the essential purposes and processes of collection and processing of personal samples and data are disclosed as part of biobank research, and the donor knows what he is agreeing to when he provides his samples and data for biobank purposes)
 - Clarify the rights of donors (personal information, use of the samples, consent withdrawal, revoking the right of use);
 - The donors would then have the possibility at all times to obtain information on the activities of the biobank and the whereabouts of their samples and data.
 - To use the dynamic consent model (developed through the EnCoRe project) to enable participants in a biobank to give consent to the use of their samples over a long period of time.
 - To not collect biological sample of died person without permission.
 - any damage would result only from discriminatory uses of the information,

5. Commercialization and Intellectual Property benefits

- the citizen donor may not have economic benefits
- The interests of the community will be guaranteed by availability of the results of research and technologies derived.
- Biobank exercises a public function which implies compliance with rules and standards established to ensure the public interest
- The biobank is independent of donors, researchers (and their sponsors) and institutions of research and health care
- The biobank provides an equitable system of access for researchers wishing to use the biobank

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* EUR 25302 EN; OECD 2010; etc