Research biobanks have tended to grow in number around the world due to two major improvements: on the one hand, the development of genetic tests, gene therapy and other innovative therapies in the field of predictive medicine; on the other hand, the promises of individual genetic profiles for personalised medicine.

Beyond these expectations and despite the existence of specific legal provisions or guidelines, many uncertainties still remain regarding the social acceptability of biobanks. Indeed, once donors’ biological samples and associated data are stored into biobanks, their scientific use as well as the way biobanks are driven give rise to three main issues.

1.- Confidentiality and privacy

How and to which extent are personal data maintained in biobanks preserved from external interference? What is the exact content of national legislations on this topic? Is a homogeneous answer possible? For example, in Sweden, any breach of confidentiality related to State interference was dismissed, but after the Tsunami in Thailand (December 2004), the Swedish parliament has voted a statute in order to allow blood samples from the Karolinska Institutet (Stockholm, Sweden) to be used for purpose of identification of Swedish victims of the disaster\(^1\).

2.- Consent issues

Prior informed consent and right of withdrawal have become the red thread of most legislations. Indeed, this legal mechanism is the cornerstone of donors’ decision to be involved/not to be involved anymore in biomedical research. Nevertheless, these legislations do not exhaust all the practical issues at stake. One the one hand, a gap remains between legislations which provide for an opt-in system and those which foresee an opt-out mechanism. On the other hand, it is not always very clear whether or why the legislator has provided for consent in specific circumstances – e.g when biological material is wasted or abandoned\(^2\); for deceased donors – or if he has provided for specific requirements when biomedical research tends to increase specific risks – e.g genetic research and discrimination risks, R&D and commercial drifts risks. Lastly, what about the exact withdrawal modalities? For example, in France, no legal provision specifies in which way donors can withdraw from the biobank whereas other models like that promoted by UK Biobank tend to establish clear and graduated withdrawal rules\(^3\).


\(^2\) It is the case in France since the August 6, 2004, Bioethics Act through articles L.1235-2 and L.1241-5 of the Public Health Code respectively related to surgical waste and foetal tissues.

\(^3\) UK Biobank provides for options for withdrawal: ‘no further contact’, ‘no further access, ‘no further use’. No further contact means UK Biobank will still have the permission to use information and samples provided previously as well as to obtain further information from their health-relevant records, but will no longer contact her/him directly. No further access means UK Biobank will no longer contact the participant or obtain further information from health-relevant records in the future, but will still have their permission to use the information and samples provided previously. No further use means that “in addition to no longer contacting the participant or obtaining further information about them, any information or samples collected previously would no longer be available to researchers, in UK Biobank Ethics and Governance Framework, version 3.0 (October 2007).
3.- Property and access

a.- Whose property?

- Property is not that of donors

According to most of European legislations – except in Portugal- the donor is not entitled with any property right in his biological material. For example, in France, raw biological material cannot be the subject matter of any property right according to the ‘no property principle’: « The human body, its elements and its products may not form the subject of a patrimonial right » (article 16-1, paragraph 3 of the civil code) associated with the interdiction of lucrative gain (article 16-6 of the civil code). This means that rough human samples cannot be appropriated by donors. Consequently, under the umbrella of the altruistic principle donors will be dismissed from any benefit in case of scientific valorisation. Is it fair or are they entitled to benefit sharing? Is there another way to entitle them with an on-going control on the use of biological material on the ground of personal rights or thanks to an in-between model (personal/property rights)?

- Is there a property for institutions and/or researchers?

If donors have no property right, who’s the owner of biological samples collections? Institutions? Researchers? In many European countries, the question whether institutions or researchers have a property right on biological material remains unclear. Certainly, they may get property rights on biological samples as long as these materials have been modified. But two main issues remain:

- From which degree of transformation can biological samples be considered as appropriated goods?
- Can institutions and/or researchers pretend to any property on raw materials for the sole reason they collected and stored them for scientific use?

These questions still give rise to very diverging viewpoints. Some consider a sample to be an appropriated good as long as an innovation is derived from human biological

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4 Lei nr.12/2005 de 26 de Janeiro, article 18 §2 states that the material stored in the biobank is “the property of the people from whom it was collected and after their death or incapacity it is the property of their family members”. Consequently, the dispute on whether DNA is a thing or still a part of the person -according to Roman categories between thing/person- does no longer exist, in P.Lobato De Faria, “Ownership rights in biobanks for research, Do we need a new kind of “biological property”?”, p.5-6 (to be published).

5 See also article 16-5 of the Civil Code which provides for the public order cancellation of extra-patrimonial agreements: “Agreements that have the effect of bestowing a patrimonial value to the human body, its elements or products are void ».

6 Art. 16-6 of the Civil Code : « No remuneration may be granted to a person who consents to an experimentation on himself, to the taking of elements off his body or to the collection of products thereof ».

7 One the one hand, academics and industry could not have developed benefits without donors’ biological material gift. On the other hand, bodily element removal uses to be undertaken by national public health system which is funded by the community and donors have only given a rough entity with a low inherent value which is added thanks to, and in proportion to, intellectual, technical, and industrial investment.

8 According to certain biobanks, it seems that preservation and conditioning activities for research purposes are in essence a transformation insofar as this activity requires highly qualified professionals and sophisticated machinery which drive up costs
material (the famous John Moore case[^9] is emblematic of this first conception). Others believe that samples can be considered as appropriated good from the moment they are stored in biobanks, because of the high degree of sophisticated technical handling they require (in this vein, see the Australia’s High Court of Justice decision in *Doodward vs. Spence* (1908), which implicitly entitled a researcher to property rights over a formaldehyde-stored foetus by giving him the right to prosecute the person who had stolen it. Judges found that the researcher had undertaken a real storage process[^10]. See also the *Catalona case* (USA) where the judges have recognized a property right in favour of the University housing a collection of prostatic samples, to the detriment of the physician who had set it up over the years[^11]).

**b. Access issues**

Access imperatives have become a core challenge in our contemporary societies (access to water, drugs, information, law, energy) according to MacPherson and J.Rifkin; they prove particularly relevant to biobanks as well[^12]. As a matter of fact, biobanks are a source of unique biological samples and a very important tool for research; for this reason, there is a quite wide consensus on the fact that their content should be available to all researchers as freely as possible.

Is property adapted to that stake? Most observers tend to agree on a negative answer for property leads to exclusivity: should a person or an institution be the unique legal owner, this could lead to a closing and blocking of this precious resource stored in biobanks.

In this context, what kind of other legal solutions should European countries turn to? Trust (or other administrative management models where biobanks are considered as a public good) reveals an interesting category. For example, in England, *UK Biobank* has provided a « stewardship model » even though it is « the legal owner of the database and the sample collection[^13] », a way to manage the biobank according to collective interests. In Spain, the legislator has provided for a steady administrative management of biobanks through the following 2007 July, 3 Act, ley 14/2007 about biomedical research. Indeed, article 65, Chapter IV (**Biobancos**) provides that the facility or person who has set up the biobank is clearly designed as the biobank administrator: it/he/she will be dismissed in case of problem, replaced at the end of its/his/her mandate or will have to inform the relevant authority in case of changing purposes in order to obtain a new authorization”.

But the trust model is not applicable in all E.U. countries’ national laws so that other mechanisms should be invented and set up in order to ensure that samples are not kidnapped by just a few persons to the detriment of the collectivity.


[^13]: “Such ownership conveys certains rights, such as the right to take legal action against unauthorized use or abuse of the database or samples, and the right to sell or destroy the samples (…) UK Biobank does not intend to exercise all of these rights; for example, it will not sell samples. Rather, UK Biobank will serve as a steward of the resource, maintaining it and building it for the public good in accordance with its purpose (…)”, in p.12, *UK Biobank Ethics and Governance Framework, Version 3.0* (October 2007).
Conclusion

The aim of the workshop is to get back to each of these three issues and highlight national answers (regulations and practices) in order to see whether an European framework can be worked out, as it is necessary to set up ethical and legal standards for social acceptability as well as for international research cooperation, which should not be hindered by disparities.