Medical research using biobanks: do we need to boost our conception of informed consent?

Rafael Vale e Reis (Portugal) rafaelvr@fd.uc.pt

Research Coordinator at the Biomedical Law Centre of the Faculty of Law, Coimbra

Within the last 20 years, biobanking has been a very developed technical activity in the health system, and that is why it is not a surprise, specially considering the possibilities (both positive and negative) brought by that enhancement, the attention that Law and Bioethics started to pay in this field.

However, it is possible to find several models for that legal intervention.

Some countries have decided to extend the scope of the protection offered by data protection legislation (data protection model). Another model deals with the regulations of biobanks offering new legislation on biomedical research.

Some legislation, like the Portuguese one, prefers to consider legal problems related to biobanks on the perspective of the procurement and use of biological material. In this case, it is also possible, at the same time, to extend the data protection rules so that they could be applicable to those samples (mixed model).

We may also find the transplantation model, where the regulation of biobanks is made from existing legislation on organ removal.

Regarding the topic of informed consent for the procurement of biological samples, some countries tend do demand a specific informed consent, and thus forbidding broad consent from the subject who contributes for the creation of a biobank.

However, this solution is controversial, and some defend that in case of research using biobanks, the traditional perspective of informed consent (as we are used to envisage it for medical treatment) should be cast way, as it is impossible to predict all the future use that can be given to the sample collected.