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LETTER TO THE EDITOR

Biobanking-related bioethical and legal unresolved issues

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Dear Editor,

We have read with interest the recent article by Annaratone et al. [1]; as members of a team involved in the project for the creation of a research biobank in the Umbria Region (Italy), we agree that such an objective is a very difficult challenge both in terms of scientific suitability, economic sustainability, and the political will to create such an infrastructure. However, before tackling these difficulties, all issues related to bioethics must be resolved, bearing in mind legal prescriptions.

In fact, in addition to what was discussed in this paper, it is important to underline that in the long process of building a biobank, many ethical and legal problems emerge.

The complexity and comprehensive reach across sectors, however, make the GDPR difficult to apply in practice, especially for health research. GDPR, while providing an important legal framework of rules for the protection of personal data, leaves many aspects related to the activity of biobanking of human biological samples uncovered, such as:

(i) The "secondary use" of data originally collected for other purposes (e.g., for medical ones) is essential in biobank activities. However, secondary use is not specifically clearly regulated by GDPR.
(ii) The GDPR does not clearly state the need to acquire "broad consent" for biobanking to ensure the use of data/material in subsequent research activities not known at the time of the collection. However, the availability of that practice seems to be suggested by the "recital" no. 33 of the GDPR [2].
(iii) Materials and data stored in "historical collections" can be useful for research activities and of particular interest to a pathology department. Nevertheless, they have been collected without prior informed consent, either for research activities or even for medical treatment, and this is in contrast with GDPR [3].
(iv) GDPR refers explicitly to "genetic data" (see Articles 4, n. 13 and Article 9 (1), GDPR), but it does not take into account the "genetic exception" because genetic information is different from other information: it is common for many individuals and has an information content that may be developed in the future [4].
(v) There is a legal uncertainty linked to the validity and sustainability of the rights of the sample transferred by the donor to the biobank and on the legal effect of a withdrawal of consent.

Moreover, GDPR has to be coordinated with other EU norms applicable in biobanking, such as Regulation (EU) 536/2014 on clinical trials or the Directive 2004/23/EC on the use of human tissues and cells.

Within the EU, it exists a debate among scholars and professionals to try to solve the above-mentioned problems. A possible solution may be the so-called "codes of conduct" in accordance with Article 40 of GDPR, drawn up by "associations and other bodies representing categories of controllers or processors" and approved by the competent supervisory authority. In this context, it has to be emphasized the role of the BBMRI-ERIC, which is elaborating on the Code of Conduct. This could help, at the EU level, to face some problems mainly linked to the balance between research needs and individuals' rights and freedoms.

Together with appropriate future change in the current legislation [5] and the adoption of an incoming Code of Conduct by BBMRI-ERIC (as well as other national or EU research organizations, e.g., EFPIA) [6], only the continuous discussion between scientists, jurists, pathologists, and

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bioethicists can find solutions to the concrete and daily problems linked to correct management of a biobank.

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Declarations

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Conflict of interest The authors declare no competing interests.

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