



Biomedicine and Law

Lecture “Processing of sensitive health and genetic data: Biobanks”

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Search online the UK Biobank website (<http://www.ukbiobank.ac.uk/>), especially sections: [Participants](#), [Resources](#), [Scientists](#)

Answer briefly the following questions based on the content of the information provided on the website:

1. Is “Informed consent” adequately addressed? Justify your answer.

In the UK Biobank, it is stated that informed consent is taken explicitly, from people mentally capable and of particular age group. As it is impossible to predict future research studies, the biobank seeks consent for the research purposes of the institution, in general, which is in accordance with its purpose and activity. The information given to the participants, clarifies the purpose of the institution, the research activity, benefits and risks that could appear during the participation. We observe here, a case of broad spectrum consent, other than a specific research objective. Anonymity, even though it is reversible, and restrictions to unauthorized persons are ensured. Research activity will be performed on the samples, only if there is approval of the study by an ethics committee, while the biobank holds the right to recontact the participants. The last also have the right to withdrawal, at any time, at different levels of the research process. A bit problematic seems to be the previously given informed consent in the case of death or loss of mental capacity, where the biobank reserves the right to continue research, even when consent cannot be guaranteed. In this case, we are led to the conclusion that human samples should be used, with the exception of previously expressed opposite wish of discontinuing future research.

2. Is “Data privacy and confidentiality” adequately addressed? Justify your answer.

UK Biobank, takes measures to protect confidentiality of data and samples. The institution, reversibly anonymises the data in order to ensure security. The protection of the sensitive data is a major ethical issue, and the most considerable risk has to do with the breach in security, which could cause trouble in the protection of the subjects, the privacy and the confidentiality. The storage of the information, in the biobank's local servers and central databases, even if the biobank's informed consent sheets ensure security and careful handling from specialised staff, with confidentiality agreements signed, does not ensure privacy. The easiness in re-linking of the participants' identifying information with their data and samples does not ensure anonymity and a possible breach could reveal information to insurance companies, employers or could stigmatise whole groups of people.

3. Is “Return of results to participants” adequately addressed? Justify your answer.

UK Biobank states that it would be possible to provide the results of certain measurements or observations, at the stage of initial assessment, regarding for example blood pressure or incidental findings, at the initial the stage before data storage and at the stage where results are derived from research studies. Such disclosure to the participants, however, is rather questionable, as the data are irrelevant to their clinical environment, without proper evaluation through the context of the study findings. Therefore, they could cause harm to the participants, filling them with anxiety or cause complications with insurance and employment situations. For these reasons, the biobank reserves the right not to disclose such information about individual results but the results would rather be available to the society, after the completion of the study and the interpretation of the results properly and in context.

4. Is “Ownership of samples or data” adequately addressed? Justify your answer.

The UK Biobank establishes the legal ownership of the database and the sample collection, having the right to take actions against unauthorized access and abuse and reserving the right to sell or destroy the samples, excluding from the participants any right over their samples. It states though that it is not in the biobank's objectives to sell the samples but rather maintain management and produce research results that will promote the public good. A certain "relationship of trust" tries to be achieved through the informed consent agreement that will lead to the participants' acceptance of the way the samples are handled and used. Ownership of the samples is an ethical consideration and many biobanks prefer to be custodians or trustees other than owners. Anonymisation could ensure that the samples are not owned, but in any other case, it is advisable for the donor to maintain the right to withdraw consent and the sample freely.

5. Is “Data sharing” adequately addressed? Justify your answer.

The UK Biobank reserves the right to retain full control over the access and the uses of the data and permit access to universities, government, charities or commercial users under certain ethical and scientific standards. It clearly states that exclusiveness of access will not be granted in any case and that the use of the primary data will be strictly controlled as the sources are limited and depletable. All findings, will be added to the biobank's database in order to become available to all research units, promoting the public health and benefit. International collaboration is important in order to facilitate research and it should be encouraged in order to find results, compare and verify them. However, the status of the data, whether they are anonymised or not, shall be expressed and the donors shall be exposed to minimum risk.

6. Is “Duration of storage” adequately addressed? Justify your answer.

The biological samples are stored in order to be used for further genetic analyses in the future. The UK Biobank retains a copy of the results data and does not pose a time limitation to the researchers for the retention of the data. It states that the destruction of the data is difficult, so it is rendered inaccessible for further use, if needed. Serious ethical considerations are raised with the fate of the biological materials and the genetic data after their analysis, whether they shall be destroyed or remain in the biobanks and for how long. The duration of the data storage shall be strictly determined in the biobanks' policy and shall be in accordance with the ethical and scientific code of conduct.

7. Is “Closure or sale of the biobank” adequately addressed? Justify your answer.

In the case that the UK Biobank will have to close or make transitions in the holdings or control of the resources, there will be the possibility of partial or full transfer of the resources, as a result of liquidation. The biobank's aim seem to be the ensurance of the protection of the participants' rights, while the procedure is controlled strictly by an ethics council. Any relevant information is to be disclosed to the participants. The fate of the biological material and the genetic data produced, in case of the biobank's closure or transfer to another entity, raises serious ethical considerations, especially when it has to do with the seeking of re-consent from the participants and the handling of the situation, so as the protection and respect of the participants' rights is ensured.

8. Is “Benefit sharing” adequately addressed? Justify your answer.

The dissemination of knowledge should be the ultimate goal of the research process and the UK Biobank states that has the objective to learn from participants' donation in order to ultimately benefit the public's health. The relevant information is to be published in scientific journals, communicated to the participants and be made available to the public as a resource for further research, with the ambition to improve techniques and processes. Furthermore, the biobank states that the intellectual property rights are to ensure the accessibility of results to all researchers, avoiding inappropriate uses and unjust constrains. The institution is committed not to patent its inventions in order to raise money but its purpose is purely scientific, retaining the right to support the development of a profitable invention. However, the stakeholders, as biotechnological and pharmaceutical companies, commercial companies and other research institutions, could be allowed to make profits, after an ethical evaluation of the relevant committee. Finally it states that any income would be re invested in the resource. Biobanks should balance the interests of the stakeholders and benefits could be shared among participants, researchers and institutions. After all, the participants' profit is the eventual improvement of their everyday life through effective diagnoses and treatments of diseases, which the research they participated in will have succeeded.