

Biomedicine and Law

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

Student: George Tsipas

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.

The consent form which I found in UK Biobank clearly states the free volunteer and withdraw at any time. Also, this form wants to assure that if the UK Biobank wants to ask more questions it will re-contact the participant. Adding the free access to the participant’s health related records for research purposes.

In my point of view, this Informed consent is not adequate addressed. It is very general. I think the consent must be altered in different cases, to be more specific consent. For example, the consent does not clarify How the participant’s parts will be used in the research. Many details are missing like the use of the data/samples if the participant die and how many researches will be with the participant’s samples/data.

Also, in the case of withdrawal this consent does not tell us how the samples are going to be taken out of the research. The UK Biobank states about the withdrawal: This means that UK Biobank would no longer contact the participant directly but would have permission to retain and use information and samples provided previously and to obtain and use further information from health records. This level of withdrawal leaves the resource intact and will allow researchers to study disease with the goal of improving the health of future generations.

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

Again, I think there is a problem with the specification of the data privacy and confidentiality. UK Biobank says that the data/samples is going to be given in external cooperators and it will be anonymously.

But, no statement about the risk to reveal the true identity of the participant and no reference about to ‘who’ are the external cooperators and in what way will be analyzed and where this sensitive information is going to be stored. Last but not least, the danger of stigmatization is not analyzed as well as how many and in what way will the participant be referred to the publications that will occur.

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

UK Biobank states that no results from the research will be given to the participant, but the participant maybe wants to know the result e.g. for a certain disease. It is the right to know or not to know. That’s why the consent must be altered in cases. So, it is not adequately addressed even if the UK Biobank leaves open the opportunity to re-contact and resolve the problems.

Another issue is that no financial gain will be taken from this voluntarily research from the participant’s point of view, but what about the UK Biobanks side and the external cooperators? In what way they will profit remains unclear.

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

I feel bad for repeating myself but it is not adequately addressed, concerning the ownership of the samples/data, again it is very general. For example if the participant withdraw, I am not sure if the samples/data will be destroyed, and from the side of the external cooperators. Although the UK Biobank states that the retrieval of the personal data will occur in case of withdraw, does not tell us in what ways and in how many cases and circumstances.

In the site of UK Biobank it says that after the consent the samples or data will be used under the judgement of the UK Biobank Policies. The ways of ownership is unclear.

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

As for the data sharing, in the website I found that the data will be given to some approved researcher but anonymously. In the website you gave us I found the guide for the data collection/sharing. It analyzes very good many questions one might have. The security of the data/samples is very good and secure.

The problem is the same with the previous question, about the use from the external cooperators.

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

It is very clear that only blood and urine samples will be used for long term storage for health related purposes/researches. The duration is not an exact time, it only refers to long term storage. Also, there is a problem with the long term storage from the external cooperators/organizations, in the site does not clearly answers the storage from third persons/organizations.

It would be adequately addressed if the participant would know how long this long term storage is and in what hands will be.

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

In the pdf (EGF Consultation 2) which I found through the website it says that the DNA samples are not to be sold to anyone/third party. Also, in the policy of the UK Biobank it says that the data/samples it would not be sold, in case of closure or sale. Clearly states that the samples would be as national resources and not as a trade opportunity. Last remark is that in the case of closure or sale it is going to be a consultation from the participants or the relatives. I think it is the most adequately addressed.

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

Concerning the issue of the determination about the benefit sharing, I think it is adequately addressed. Because in the section about benefit sharing, the sharing of benefits it is analyzed very carefully. I see percentages and many tables which they are stating the exact sharing percentage depending the case. It also has many changes, if the participant want something else or if he has a problem with something.

It is important to be noted that in all of the questions that you gave us, the UK Biobank gives the opportunity to tell your problems and to fix them in a way, if they can. In almost all cases/problems the UK Biobank gives the consultation ability in order to cover the participant at any point.