

Survey and focus group questions

Survey questions¹

Preamble

And now thinking about biobanks for biomedical research: These are collections of biological materials (such as blood and/or tissues) and personal data (medical records, lifestyle data) from large numbers of people. Using biobanks, researchers will try to identify the genetic and environmental factors in diseases, to improve prevention, diagnosis and treatment. Participation in biobanks is voluntary. Critics, however, raise questions about privacy, confidentiality and commercial interests regarding the biobanks and about who is going to regulate them.

Participation

Would you be willing to provide information about yourself to a biobank?

- a. Yes, definitely
- b. Yes, probably
- c. No, probably not
- d. No, definitely not

Consent

In a hospital doctors ask the patient to sign a form giving permission to carry out an operation – this is called ‘informed consent’ and it is also required of medical researchers who do research involving members of the public.

When a scientist does research on data in a biobank, what do you think about the need for this kind of permission? Researchers should...

- a. Not need to ask for permission
- b. Ask for permission only once
- c. Ask for permission for every new piece of research

Engagement

1. Before today, have you ever heard anything about biobanks?
 - a. Yes
 - b. No

(If yes...) Have you ever..?

2. Talked about biobanks with anyone before today?
3. Searched for information about biobanks?

¹Gaskell G, Stares S, Allansdottir A, *et al*: Europeans and biotechnology in 2010: Winds of change. European Commission, Eurobarometer, EUR 24537, Luxembourg: Publications of the European Union, 2010. See also <http://www.stepe.eu>.

- a. Yes, frequently
- b. Yes, occasionally
- c. Yes, only once or twice
- d. No, never

Governance

Biobanks will follow up participants over long periods of time. And many biobanks will work with industrial companies to develop new medicines. Who do you think should be primarily responsible for protecting the public interest? Firstly?

- a. Medical doctors
- b. Researchers
- c. Public institutions (universities, hospitals)
- d. National governments
- e. Ethics committees
- f. International organisations such as the European Union or World Health Organisation
- g. National Data Protection Authorities

Trust

For each of the following people and groups, do you think they are doing a good job for society or not doing a good job for society?

- a. Industries which develop new products with biotechnology
- b. University scientists who conduct research in biotechnology
- c. (NATIONALITY) Government making laws about biotechnology
- d. The European Union making laws about biotechnology for all EU Member States
- e. Ethics committees who consider the moral and ethical aspects of biotechnology
- f. Religious leaders who say what is right and wrong in the development of biotechnology
- g. Medical doctors

Data privacy

In order to understand the causes of diseases researchers need as much information as possible about the people in the biobank. Would you personally be concerned or reluctant about the collection of any of the following types of data and materials from you?

- a. Blood samples
- b. Tissue collected during medical operations
- c. Your genetic profile
- d. Medical record from your doctor
- e. Lifestyle (what you eat, how much exercise you take, etc.)

Focus group topic guide

This topic guide was used for both lay and informed public groups and the questions on participation (Theme 2) were adapted for those informed public groups that had participated in a biobank such as for example UK Biobank.

THEME 1: What are Biobanks?

- Biobanks are collections of human body samples (e.g. tissue, DNA, blood, etc.) that get linked with other donors' data administrated in data bases.
- Biobanks store huge amounts of biological data such as DNA, blood or tissue together with donors' background information such as health history or conditions of living.
- If biobanks collect and operate with samples for medical research, some form of donors' consent is necessary.
- Biobanks are infrastructures for medical research. Future research aims can often not be foreseen at the moment of up-building.

“New technological developments such as the development of biobanks often have both positive and negative sides to them. We are interested in gathering your first impressions of possible and negative sides to biobanks. Could you write one of each down, each on a separate post-it? We're interested in your first impressions, so please write down the first thing that comes to your mind.”

THEME 2: Participation

Case (case varied slightly according to national context)

The biobank in this case study takes the form of a long-running scientific investigation. The premise of this research project is that the occurrence of chronic diseases – such as asthma, diabetes or kidney diseases – is a result of a complex interplay of factors. Hereditary predisposition plays a role in this, but also so-called environmental variables – such as overweight [obesity], physical exercise, nutrition, smoking, et cetera – are important in this respect. Only an approach that takes all these factors into consideration can provide insight in the occurrence and course of chronic diseases. This may result in better, more personally tailored, prevention strategies and treatment.

However, for this type of research, a large group of people from multiple generations needs to be followed for an extended period of time. That is why the biobank at first aims at gathering about 45.000 participants. Participants' data will be gathered using questionnaires, physical examination and lab tests. Participants will fill in an extended questionnaire on their current state of health, past diseases, and the existence the participant's and her/his family members' risk factors. Moreover, a number of questions relating to physical exercise, lifestyle and matters such as the use of pharmaceuticals will also be posed. Among other things, the physical examination will focus on weight, length, diameter of stomach and hip, so that an estimation of (over)weight and fat distribution can be made. During the visit, blood pressure will also be measured. Furthermore, a heart film and a lung function will be investigated. Finally, blood will be tapped while the participant is sober to determine fat and glucose concentration. Also, participants will hand in a urine sample.

“Would you participate in a research project like this one?”

THEME 3: Under which conditions should biobanks operate?

Subtheme 1: Privacy

Dilemma 1 (privacy)

In the research conducted by biobanks, personal information, such as personal physical characteristics, are linked to biological data. This is important for the research. Also, your name and address will be known to the biobank, so that you and your GP can be informed of the most important results of the research, such as results of the lung function test, blood pressure and blood tests for cholesterol and sugar level. However, this may also mean that further research results can be traced back to you personally.

“Would you be concerned about the coupling between personal information and biological data?”

Subtheme 2: Informed Consent

Dilemma 2 (informed consent) (case varied slightly according to national context)

This large biobank research will be conducted repeatedly with the same participants (once every 5 years). Furthermore, in the future smaller groups of participants will be asked to participate in additional research, like f.i. a glucose strain test for tracking down diabetes more precisely, or an extended investigation of the lung function. Because of the long term in which research is conducted, and because it is difficult to predict what kind of developments will ensue, the type of research that the biobank will be conducting is not yet known. The biobank asks you for your permission to use your information for future research. [additional information on consent types on flip chart]

What kind of consent would you provide for this type of research?

Subtheme 3: benefit sharing

Participation in the research takes place on a voluntary basis. The uptake of one's personal information is often regarded as a donation or a gift.

Do you think participants should get something in return for participating in such research?

Subtheme 4 Commercialization

There is a possibility that information and results of the biobank will in the future be used for commercial purposes.

Should personal information and research results from a biobank be used for commercial purposes?

Subtheme 5 Internationalization/Transnationalization

Since increasing use is being made of biobanks and since biobanks are getting ever larger, data and tissue exchange is growing steady as well. This is considered important since every biobank will then have access to much more data and will be able to conduct more and better research. Biobanks aim at collaborating more on an international level as well.

Do you see international collaboration between biobanks as a positive or a negative development?

THEME 4: Governance/Regulation

“There are many different parties who could play role in running or governing affairs concerning biobanks. One can think here of the biobank itself, international organisations, or ethical commissions. Which party should have the upper hand in this? Who should have the main/most responsibility?”