

## True/False Comprehension Assessment for Biobanking - English

This quiz was empirically developed to reflect content identified by an expert Delphi panel and was used to assess comprehension among individuals given a simplified versus traditional biobank consent form. For details, please see:

- Beskow LM, Dombeck CB, Thompson CP, Watson-Ormond JK, Weinfurt KP. Informed consent for biobanking: consensus-based guidelines for adequate comprehension. *Genet Med*. 2015 Mar;17(3):226-33. doi: 10.1038/gim.2014.102.
- Beskow LM, Lin L, Dombeck CB, Gao E, Weinfurt KP. Improving biobank consent comprehension: a national randomized survey to assess the effect of a simplified form and review/retest intervention. *Genet Med*. 2017 May;19(5):505-512. doi: 10.1038/gim.2016.157.

*\*\*\*As with any consent template materials, be sure to customize to your needs before using!\*\*\**

This work was supported by a grant (R01-HG-006621) from the National Human Genome Research Institute (NHGRI). The content is solely the responsibility of the authors and does not necessarily represent the official views of NHGRI or the National Institutes of Health.

The format for this document is:

### **INFORMED CONSENT TOPIC AREA**

*Delphi statement:* A statement of the essential information a prospective participant should know about the consent topic, with the key informational elements in **blue**.

1. Quiz item to assess knowledge of essential information

**A (CORRECT ANSWER):** Initial version of the quiz item

**B (CORRECT ANSWER):** Alternate version of the same quiz item to be used for re-testing among those who answer the initial version incorrectly

2. For compound Delphi statements, there are separate quiz items to address the different components

## BIOBANK PURPOSE

*Delphi statement:* “The purpose of this project is to collect and store samples and health information for use in future research.”

1. Collect and store samples and health info

**A (TRUE):** The purpose of the Biobank is to collect and store samples and health information.

**B (FALSE):** The Biobank will not store any samples or health information.

2. Used in future research

**A (FALSE):** The materials in the Biobank will not be used for any future research.

**B (TRUE):** The materials in the Biobank will be used in future research.

## BLOOD DRAW

*Delphi statement:* “You are going to draw blood from me.”

3. Draw blood

**A (FALSE):** I will not have to give blood as part of this project.

**B (TRUE):** I will have blood drawn as part of this project.

## COLLECTION OF INFORMATION

*Delphi statement:* “You will ask me some basic information and will contact me to update this information. You will also collect information from my medical records.”

4. Ask for basic information

**A (TRUE):** The Biobank will ask me for some basic information about myself.

**B (FALSE):** I will not be asked to provide any information about myself to the Biobank.

5. Contact to update

**A (FALSE):** After getting some basic information from me, the Biobank will not contact me again.

**B (TRUE):** The Biobank will contact me to update my basic information.

6. Collect info from medical records

**A (TRUE):** The Biobank will collect information from my medical records.

**B (FALSE):** The Biobank will not collect information from my medical records.

## DURATION OF STORAGE

*Delphi statement:* “My sample and information will be **stored forever** unless I decide to **stop taking part.**”

7. Stored forever unless stop taking part

**A (TRUE):** Unless I decide to stop taking part, my sample and information may be kept in the Biobank for an unlimited amount of time.

**B (FALSE):** My sample and information will not be kept in the Biobank for more than one year.

## ACCESS TO BIOSPECIMENS / DATA

*Delphi statement:* “Researchers may **study** my samples and information. You will not give researchers information that could **identify** me.”

8. Researchers may study

**A (TRUE):** Researchers may study my samples and information.

**B (FALSE):** My samples and information will not be used for research.

9. No identifiers given

**A (FALSE):** Researchers will be able to easily identify me using the information they get from the Biobank.

**B (TRUE):** The Biobank will not give researchers information that directly identifies me.

## RECONTACT

*Delphi statement:* “Someone from the **biobank may contact me** about participating in **additional research.**”

10. Biobank contact about additional research

**A (TRUE):** Someone from the Biobank may contact me about participating in additional research.

**B (FALSE):** The Biobank will not contact me about participating in any additional research.

## LARGE-SCALE DATA SHARING

*Delphi statement:* “Some of my information might be put into a **database**. There is a **small chance** that someone could trace my information **back to me**.”

### 11. Information put in database

**A (FALSE):** None of my genetic or health information will ever be put into a database outside the Biobank.

**B (TRUE):** Some of my genetic and health information might be put into a database outside the Biobank.

### 12. Small chance could be traced back

**A (FALSE):** Someone could easily trace information in a database outside the Biobank back to me.

**B (TRUE):** There is a small chance that someone could trace information in a database outside the Biobank back to me.

## RISKS

*Delphi statement:* “There is a risk that someone could get **access to information about me**.”

### 13. Could get information

**A (TRUE):** There is a risk that someone could get access to information the Biobank has about me.

**B (FALSE):** Because of the security protocols in place at the Biobank, there is no risk that someone could get access to information the Biobank has about me.

## CONFIDENTIALITY PROTECTIONS

*Delphi statement:* “You will take many steps to **protect my privacy**.”

### 14. Privacy protected

**A (TRUE):** The Biobank will take many steps to try to protect my privacy.

**B (FALSE):** There is nothing the Biobank will do to try to protect my privacy.

## GENETIC INFORMATION NON-DISCRIMINATION ACT (GINA)

*Delphi statement:* “There is a **law** against **discrimination** based on my information.”

*Alternate Delphi statement:* There is nothing in this section a prospective participant must understand to give valid consent.

15. Law against discrimination

**A (TRUE):** Some types of discrimination based on my information are prohibited by law.

**B (FALSE):** There are no laws against discrimination based on my information.

## CERTIFICATE OF CONFIDENTIALITY

*Delphi statement:* There is nothing in this section a prospective participant must understand to give valid consent.

## POTENTIAL BENEFITS

*Delphi statement:* “I should **not expect to benefit** from this research.”

16. Not expect benefits

**A (FALSE):** Research done through the Biobank will provide me with personal health benefits.

**B (TRUE):** I should not expect to get personal health benefit from research done through the Biobank.

## COSTS AND PAYMENTS (COMMERCIALIZATION)

*Delphi statement:* “I will **not get money** from anything that is done using my sample.”

17. Not get money

**A (FALSE):** If the research leads to any new products, I will get part of the profits.

**B (TRUE):** I will not get any profits if the research leads to any new products.

## RETURN OF RESULTS

*Delphi statement:* “I should **not expect to get** individual results back from this research.”

18. Not expect results

**A (TRUE):** I should not expect to get individual results back from research done using my sample.

**B (FALSE):** Researchers who are using my sample will provide me with individual results.

## DISCONTINUING PARTICIPATION

*Delphi statement:* “I have the **right to leave** the project. However, I **cannot withdraw or get back** samples and information from studies that have already begun.”

19. Right to leave

**A (FALSE):** Once I sign up, I cannot leave the Biobank.

**B (TRUE):** I have the right to leave the Biobank.

20. Cannot withdraw samples/info already in use

**A (TRUE):** If I decide to leave the Biobank, the Biobank cannot get back samples and information that have already been given out for researchers to study.

**B (FALSE):** If I decide to leave the Biobank, the Biobank will be able to get back samples and information it has given out for researchers to study.

## QUESTIONS OR PROBLEMS

*Delphi statement:* “There is someone I **can contact** if I have **questions or want more information.**”

21. Contact for questions, more info

**A (TRUE):** There is someone I can contact if I have questions or want more information.

**B (FALSE):** I will not be able to ask questions or get more information about the Biobank later.