Appendix A: Simplified Consent

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using human tissue samples, such as blood. Through these studies, researchers hope to find new ways to detect, treat, and maybe prevent or cure health problems. Some of these studies may be about how genes affect health, or how genes affect response to treatment. Some of them may lead to new products, such as drugs or tests for diseases.

A “biobank” is a collection of stored samples and information. We are asking you to let us store some of your blood and health information in the Duke Biobank. This is because you have been a patient of the Duke University Health System.

You can take part in this storage project or not. This consent form gives information to help you decide. Please read it carefully and take all the time you need to make your choice. Be sure to ask us as many questions as you want.

Everyone who takes part in research should know that:

- Taking part may involve some risks.
- Taking part is voluntary. If you choose to take part, you can quit at any time.
- No matter what you decide, now or in the future, it will not affect your medical care.

WHY IS THIS PROJECT BEING DONE? The purpose of the Biobank is to collect and store blood and health information so researchers can use them in future studies.

WHAT IS INVOLVED? If you agree to take part, we will ask you to sign this form. We will give you a signed copy to keep. Here is what will happen next:

1. We will get a blood sample from you. We will use a needle to draw about 3 tablespoons of blood from your arm.
2. We will get some information about you and your health.
    - We will ask you for some basic information, such as your name, age, race, and family health history. We will contact you no more than once a year to update this information.
    - We will get some information from your medical record. Examples include test results, medical procedures, images (such as X-rays), and medicines you take. We will use your medical record from time to time to update this information.
    - We will get research data from any studies done using your sample and information.
3. We will store your sample and information in the Biobank, along with those from all the other people who take part. There is no limit on the length of time we will keep them. We may go on using them for research unless you decide to stop taking part in the Biobank.
4. We will let researchers use the materials stored in the Biobank for approved studies. Researchers from Duke, other universities, the government, and drug- or health-related companies can apply to use the materials. A science committee at the Biobank will review each request. There will also be an ethics review.

   We will not give researchers your name or other information that could directly identify you.

5. We may contact you about additional research. We will not notify you every time your sample and information are used in a study. However, the Biobank may contact you with offers to take part in other research. There will be a new consent form just for these other studies, so you can decide then to take part or not.

   We will contact you about no more than two other studies per year.

6. Some of your genetic and health information may be put into scientific databases outside the Biobank, along with that from many other people. Information that could directly identify you will never be included. However, because your genetic information is unique to you, there is a chance that someone could trace it back to you. We believe the chance this will happen is very small. But the risk may grow in the future if people come up with new ways of tracing information.

WHAT ARE THE POSSIBLE RISKS? The most common risks of drawing blood are brief pain and bruising.

There is a risk that someone could get access to the data we have stored about you. In some cases, it could be misused. We believe the chance this will happen is very small, but we cannot make guarantees.

WILL MY INFORMATION BE KEPT PRIVATE? Your privacy is very important to us and we will make every effort to protect it. Here are just a few of the steps we will take:

- We will remove your name and other identifiers from your sample and information. We will replace them with a code number. There will be a master list linking the code numbers to names, but we will keep it separate from the samples and information.
- Researchers who study your sample and information will not know who you are. They must also promise that they will not try to find out who you are.
- We will not give information that identifies you to anyone, except if required by law. Information that is shared outside Duke may no longer be protected by the federal privacy law called ‘HIPAA’. But it will be protected as described in this form and may be covered by other privacy laws.

There is a federal law called GINA that makes it illegal for employers and health insurers to discriminate against you based on your genetic information. GINA will not protect you from discrimination if you apply for other kinds of insurance, such as life or disability insurance.

We also got a Certificate of Confidentiality from the federal government. This will help us fight any legal demand (such as a court order) to give out information that could identify you.

ARE THERE ANY BENEFITS? You will not get direct benefit. The main reason you may want to take part is to help researchers make discoveries that might help people in the future.

ARE THERE ANY COSTS OR PAYMENTS? There are no costs to you or your insurance. We will give you a $25 gift card to thank you for your time.

If any of the research leads to new tests, drugs, or other commercial products, you will not get any profits.

WILL I FIND OUT THE RESULTS OF THE RESEARCH? You should not expect to get individual results from research done using your sample. Research is not the same as medical care.

If we discover something that is very important to your health right now, we will try but cannot promise to contact you. You can get general news about the kinds of studies being done through the Biobank at www.dukebiobank.edu.

WHAT ARE MY OPTIONS? Taking part in the Biobank is your choice. You can choose to take part or not take part.

WHAT IF I CHANGE MY MIND? You can leave the project at any time. Just call 919-666-3434 and let us know.

Please note that if we have already given out some of your sample and information for researchers to study, we cannot get them back. But we will send you a form so you can tell us what to do with any of your materials that are left in the Biobank.

WHAT IF I HAVE QUESTIONS? For questions or more information about this project, contact Dr. Erica Lee, the Biobank Director, at 919-555-1212. For questions about your rights as a research participant, contact the Duke University Health System Institutional Review Board at 919-777-5656.

Appendix B: Traditional Consent

Medical researchers are trying to learn more about cancer, heart disease, diabetes, and other health problems. Much of this research is done using human tissue samples (such as blood) and health information. Researchers often study blood and information from people who have health problems and from people who do not. Through such studies, they hope to find new ways to detect, treat, and maybe even prevent or cure health problems. Some of these studies may be about how genes affect health, or how genes affect response to treatment. (Genes, which are made up of DNA, have all the information needed to build and operate a human body.) Some of the studies may lead to new products, such as drugs or tests for diseases.

A “biobank” is a collection of stored samples and information. This collection is called the Duke Biobank (or just “the Biobank” in the rest of this form). The director of the Biobank is Dr. Erica Lee.

You are being asked to contribute a blood sample and health information to the Duke Biobank. This is because you have been a patient of the Duke University Health System.

Research projects like the Duke Biobank include only those people who choose to participate. The purpose of this consent form is to give you information to help you decide if you want to participate. Please read it carefully and take your time making your decision. As the Biobank staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research project. The nature of the project, risks, inconveniences, discomforts, and other important information about the project are listed below.

Everyone who takes part in research should know that:

- Research is intended to gain new knowledge. You may or may not benefit from participating. Participating may also involve some risks.
- Participating in research is completely voluntary. You can choose not to participate. If you choose to participate, you can discontinue at any time.
- No matter what you decide, now or in the future, it will not affect your medical care.

WHY IS THIS PROJECT BEING DONE?

The purpose of the Biobank is to collect and store human tissue samples (such as blood) and health information. The stored materials will then be used by researchers in future studies.

The goal is to have at least 20,000 people enroll in the Biobank.

WHAT IS INVOLVED IN THIS PROJECT?

If you agree to participate, you will be asked to sign this consent form. You will be given a signed copy of the consent form to keep. Here is what will happen next:

1. <u>We will get a blood sample from you</u>. We will draw 50 ml (about 3 tablespoons) of blood from a vein in your arm by needle stick.

   From this sample, the Biobank will be able to get things like plasma, serum, blood cells, DNA, and RNA. ‘DNA’ is short for deoxyribonucleic acid. DNA stores information in the form of a code. This is the code that you inherit from your parents and that you pass on to your children. Parts of DNA that have complete messages are known as ‘genes.’ Genes give the instructions for building the proteins that make our bodies work.

2. We will ask for some information about you and your health.
   - First, we will ask you to fill out a Biobank Questionnaire. This questionnaire asks for some basic information, such as your name, age, racial and ethnic groups, and family health history. We will contact you no more than once a year to update this information. This will happen for as long as your information is stored in the Biobank.
   - Second, we will collect some information from your medical records at Duke. Examples include information about lab results, medical procedures, images (such as X-rays), and medications. This is because future researchers need to know if you have any health problems. They may also need to know about any treatments you have had and how well the treatments worked. We will look at your medical record from time to time to update this information. This will happen for as long as your information is stored in the Biobank.
   - Third, we will collect research data from any future studies done using your sample and information.
3. We will store your sample and information in the Biobank. Your blood and information will be kept in the Biobank along with those from all the other people who participate. They will be stored indefinitely. We will keep using them for research as long as they are useful, unless you decide to stop participating or we close the Biobank.
4. We will let researchers use the materials stored in the Biobank for approved studies. Researchers can apply to study the samples and information stored in the Biobank. This includes researchers from Duke University, as well as from other universities, the government, and drug- or health-related companies. Some researchers will be from the U.S., some may be from other countries around the world.

   Each application will be reviewed by a science committee at the Biobank. An ethics review will also be done. This kind of review is to make sure that risks are minimized and that the rights and welfare of people who participate in research are protected.

   If a study is approved, a part of your blood and some information about your health might be distributed to the researchers, along with samples and information from many other people. We will not give researchers your name or any other information that could directly identify you without your permission.
5. We may contact you in the future with offers to participate in additional research. You will not be notified every time your sample and information are used in a study. However, some researchers might apply to do a study for which they would need to contact you. For example, they might want to ask you to give another sample or to fill out a survey. Or they might ask you to do a phone interview or come in to be seen by a researcher or doctor.

   If a study like this is approved, the Biobank will contact you first. We will tell you about the study so you can decide whether it is okay for us to give the researcher your name. If you give permission, the researcher will then contact you to tell you more about the study. There will be a new consent process just for that study. You can decide then whether to participate or not.

   We will make sure researchers do not contact you about more than two studies like this per year.
6. Some of your genetic and health information may be placed in scientific databases outside the Biobank. In order to do more powerful research, it is often helpful for researchers to share data they get from studying tissue and health information. They do this by putting it

into one or more scientific databases, where it is stored along with data from other studies. Researchers can then study the combined information to learn even more about human health and disease.

If you agree to participate in the Biobank, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of databases where your information may go. Some are maintained by academic institutions, some by the federal government, and some by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.”

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. Nobody will know just from looking at a database that the information belongs to you.

However, because your genetic information is unique to you, there is a chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future if people come up with new ways of tracing information. Researchers will always have a duty to protect your privacy and to keep your information confidential.

WHAT ARE THE POSSIBLE RISKS OF THIS PROJECT?

<u>Physical Risks</u>. Like any other time you have blood drawn, you may feel brief pain or have some bruising from the needle. Infection, excess bleeding, clotting or fainting is also possible, but unlikely.

<u>Privacy Risks</u>. There is a risk that someone could get access to the data we have stored about you. If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse, but they may not give full protection. There may be other unforeseen privacy risks.

We believe the chance these things will happen is very small, but we cannot make guarantees.

WILL MY INFORMATION BE KEPT PRIVATE?

Federal privacy rules give safeguards for privacy, security, and authorized access. We will not give information that identifies you (name, social security number, address, telephone number, or any other direct personal identifier) to anyone without your permission, except if required by law.

Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. Here are some of the steps we will take:

- We will remove your name and any other information that could directly identify you from your sample and information. We will replace this information with a code number. There will be a master list linking the code numbers to names, but it will be kept separate from the samples and information.
- Samples will be kept in locked freezers in locked buildings. Health information and research data will be kept on secure computers with very limited access. These computers have many levels of password protection. All Biobank staff sign a pledge to keep your identity a secret.
- Research records are separate from medical records. No information that we get or create as part of this project will be placed in your medical record.

- Researchers who study your sample and information will not know who you are. They will be given only a code number and not any information that directly identifies you. The researchers must sign an agreement that they will not try to find out who you are. They must also promise to keep the coded materials secure.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Duke University Health System and the Duke University Health System Institutional Review Board. A reviewer who looks at your research record may also need to look at your entire medical record. Your information may also be disclosed to outside reviewers for monitoring purposes. If this happens, it may not be covered by federal patient privacy rules (called 'HIPAA'), but it will be protected by other federal privacy rules.

Genetic Information Nondiscrimination Act. There is a Federal law, called the Genetic Information Nondiscrimination Act (GINA), that makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

- Health insurance companies and group health plans may not request genetic information from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Certificate of Confidentiality. To further protect you, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the Biobank cannot be forced to disclose information that may identify you, even by subpoena. A "subpoena" is a command to give information to a judge or court. The Biobank will use the Certificate to resist any demands for information that would identify you, except as explained below.

- The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).
- In addition, we will disclose information about you without your consent if the information is something that the law says we must report to state health officials or the state attorney's office. For example, we have to report sexually transmitted diseases, domestic violence, child abuse, elder abuse, and threats to harm yourself or others.

You should understand that a Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in the Biobank.

ARE THERE ANY BENEFITS?

You should not expect to get direct health benefits if you decide to participate in the Biobank. The main reason you may want to participate is to help researchers make discoveries that might benefit people in the future.

ARE THERE ANY COSTS OR COMPENSATION?

There are no costs to you or your insurance for participating in the Biobank. We will give you a $25 gift card to pay you for the time it took for you to join the Biobank.

Your sample and information will be used only for research. You should know that research sometimes leads to discoveries that may one day have commercial value. For example, research could lead to new tests, drugs, or other medical products. By agreeing to participate in this project, you authorize the Biobank to make your samples and information available for these uses.

In the event that research using samples and information stored in the Biobank leads to a product that could be sold commercially, there are no plans to compensate you. Development of new products usually relies on the study of samples and information from hundreds or thousands of people, not on any one person. Researchers, Duke University, and/or others may own these products and profit from their sale.

The Duke University Health System and/or the developers will assert all rights of ownership in the samples and information, as well as all rights arising from use of the samples and information.

WILL I FIND OUT THE RESULTS OF THE RESEARCH?

You should not expect to get individual results from research done using your samples and information. Researchers must study materials from many people over many years before they can know if the results have meaning. The results will not affect your care right now. They will not be given to your doctor and will not be put in your medical record.

There is a small chance that researchers could discover something that might be very important to your health or medical care right now. For example, they might find that you have a condition not previously diagnosed. Or they might find that you have a gene or other risk factor that is known to increase the chance that you or a member of your family could get a disease in the future.

We will offer to tell you a finding like this only if it is about a serious disease for which a treatment is available. We will send a letter by certified mail asking you to contact Dr. Lee, the Biobank director. Dr. Lee will arrange a time for you to meet with her or another health care provider to go over the information. Notification will be sent to the last address you provided to us. Therefore it is important that you inform us of any change in your address. Research findings will not be released over the telephone or by mail or email.

It is important to note that, even if we find something important to your health, we cannot guarantee that you will be contacted. Research is not the same as medical care. If we do not contact you about your results, do not assume that means everything is okay. Talk to your doctor if you have any questions or concerns about your health.

You can get general news about the kinds of studies being done through the Biobank at www.dukebiobank.edu and a quarterly newsletter that you will receive if you join the Biobank.

WHAT ABOUT MY RIGHT TO DECLINE PARTICIPATION?

Participating in the Biobank is completely voluntary. You can choose to participate or not participate. No matter what you decide, now or in the future, it will not affect your medical care. Refusing to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled.

WHAT ABOUT MY RIGHT TO WITHDRAW FROM THIS PROJECT?

If you agree to participate in the Biobank, you have the right to discontinue participation at any time. If you decide you want to withdraw, please contact the Duke Biobank office at 919-666-3434. We will ask you to indicate in writing on an official participant withdrawal form if you want your unused blood to be destroyed or if your blood (with all identifying information removed that would link the sample to you) could continue to be used for research.

Please note that if we have already distributed some of your sample and information for researchers to study, we cannot get them back. Also, we cannot destroy knowledge already gained from the study of samples and information. But if you change your mind about participating in the Biobank, you can tell us not to give your materials out for any more studies.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You should feel free to ask any questions. Your questions should be answered clearly and to your satisfaction.

For questions or more information about this project, or if you have complaints, concerns or suggestions about the research, contact Dr. Lee at 919-555-1212 during normal business hours. You can also call the Duke Biobank office at 919-666-3434. You can leave a message at these numbers after hours, on weekends, and on holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board Office at 919-777-5656.

Appendix C: Readability Characteristics

	Simplified Form	Traditional Form	Average of Actual Forms[i] *(Min – Max)*
Counts:			
Words	1,250	3,126	3,108 *(2,496 - 3,653)*
Characters	5,697	15,322	15,226 *(12,427 - 17,929)*
Paragraphs	39	75	93 *(73 – 142)*
Sentences	90	190	185 *(161 – 204)*
Averages:			
Sentences/Paragraph	2.6	2.7	2.6 *(2.1 - 2.9)*
Words/Sentence	13.5	16.2	15.9 *(12.7 - 17.4)*
Characters/Word	4.4	4.7	4.7 *(4.6 - 4.8)*
Readability:			
Passive Sentences[ii]	11%	24%	24% *(22 - 27%)*
Reading Ease[iii]	67.2	54.8	56.5 *(52.6 - 61.8)*
Grade Level	7.2	9.6	9.3 *(8.3 - 10.2)*

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[i] Source: Publicly available forms from 4 nationally-recognized biobanks
[ii] Active sentences are easier to understand
[iii] 100-point scale; higher score = easier to understand

Appendix D: Delphi Statement of Adequate Comprehension, Corresponding Quiz Items

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

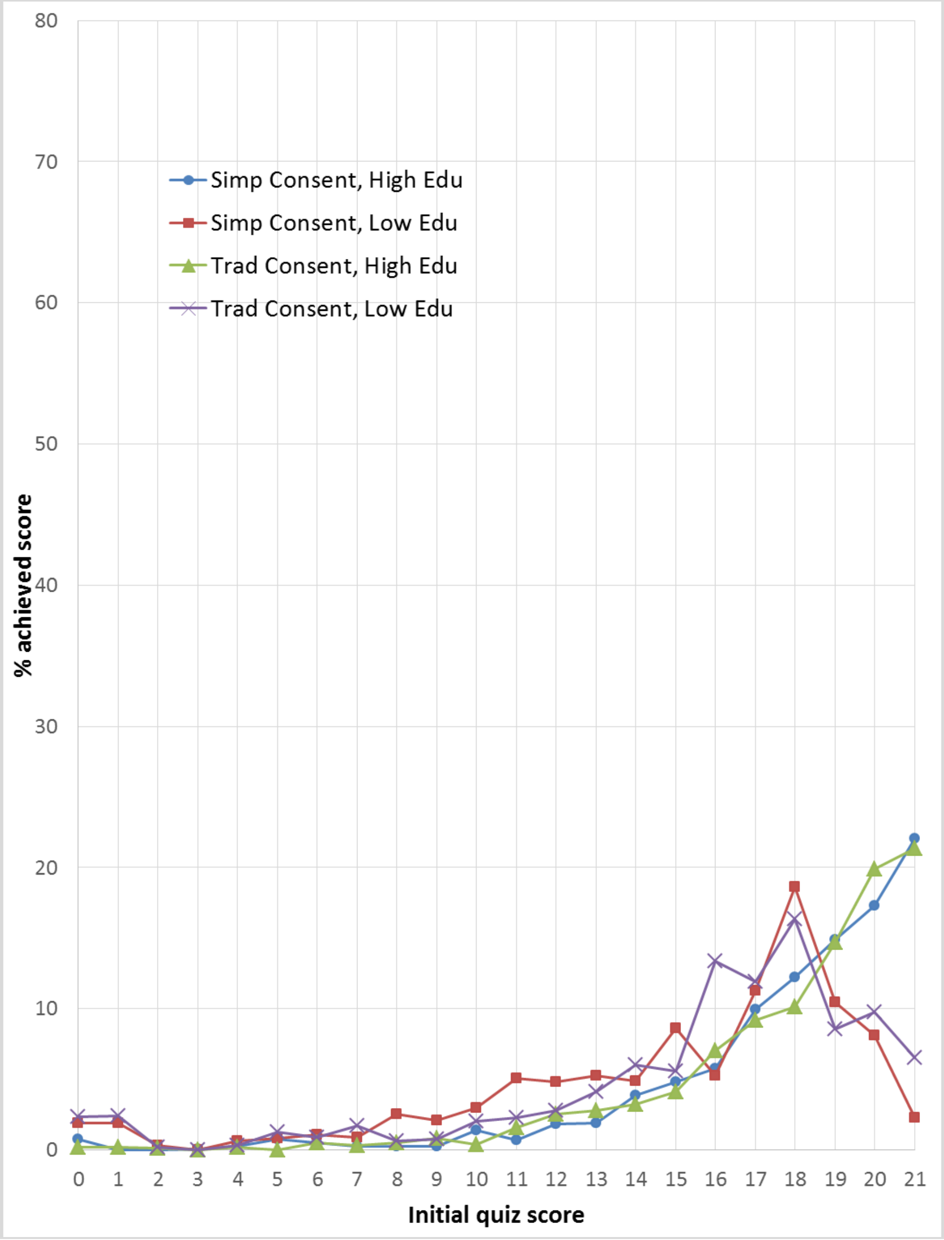
Delphi statement: “There is someone I **can contact** if I have **questions or want more information**.”

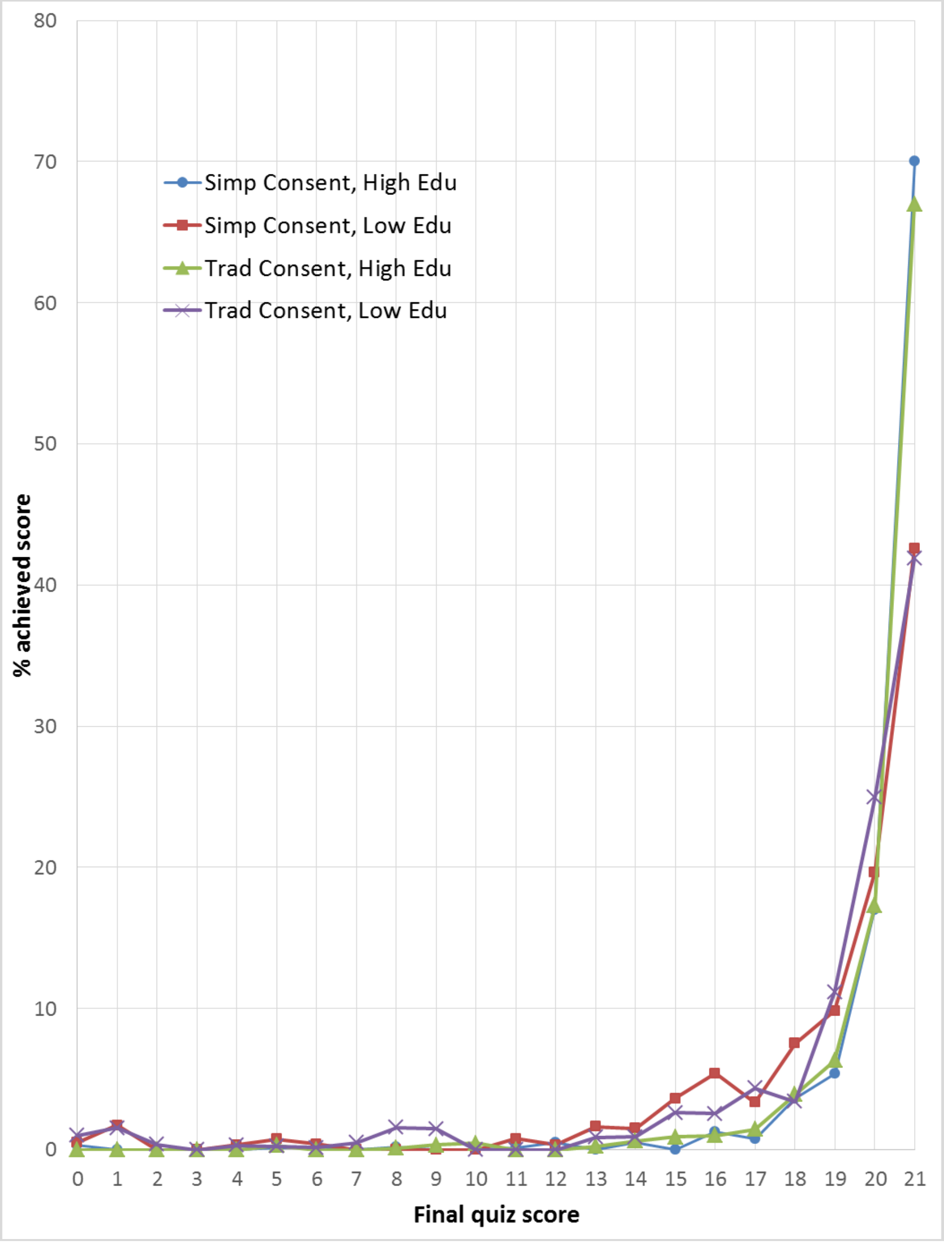
21. Contact for questions, more info

    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.

Appendix E: Initial and Final Quiz Score Frequencies (weighted)





Appendix F: Itemized Quiz Results

Quiz Item	Response	Overall (n=1916)		Simplified Form (n=969)		Traditional Form (n=947)		p-value
		n	%	n	%	n	%	
[QUIZ 1] The purpose of the Biobank is to collect and store samples and health information.	-1 = Refused	1	(0.00)	1	(0.00)			0.33
	1 = True	**1725**	**(0.90)**	**866**	**(0.89)**	**859**	**(0.91)**	
	2 = False	118	(0.06)	61	(0.06)	57	(0.06)	
	3 = Don't know	72	(0.04)	41	(0.04)	31	(0.03)	
[RE-QUIZ 1] The Biobank will not store any samples or health information.	-1 = Refused	0						
	1 = True	18	(0.09)	6	(0.06)	12	(0.14)	0.19
	2 = False	**139**	**(0.73)**	**79**	**(0.77)**	**60**	**(0.68)**	
	3 = Don't know	34	(0.18)	18	(0.18)	16	(0.18)	
Final total answered Q1 correctly:		1864	(0.97)	945	(0.98)	919	(0.97)	
[QUIZ 2] The materials in the Biobank will not be used for any future research.	-1 = Refused	0						0.05
	1 = True	123	(0.06)	68	(0.07)	55	(0.06)	
	2 = False	**1702**	**(0.89)**	**847**	**(0.87)**	**855**	**(0.90)**	
	3 = Don't know	91	(0.05)	54	(0.06)	37	(0.04)	
[RE-QUIZ 2] The materials in the Biobank will be used in future research.	-1 = Refused	0						
	1 = True	**158**	**(0.74)**	**94**	**(0.77)**	**64**	**(0.70)**	0.22
	2 = False	22	(0.10)	15	(0.12)	7	(0.08)	
	3 = Don't know	34	(0.16)	13	(0.11)	21	(0.23)	
Final total answered Q2 correctly:		1860	(0.97)	941	(0.97)	919	(0.97)	
[QUIZ 3] I will not have to give blood as part of this project.	-1 = Refused	0						0.04
	1 = True	127	(0.07)	76	(0.08)	51	(0.05)	
	2 = False	**1712**	**(0.89)**	**852**	**(0.88)**	**860**	**(0.91)**	
	3 = Don't know	77	(0.04)	41	(0.04)	36	(0.04)	
[RE-QUIZ 3] I will have blood drawn as part of this project.	-1 = Refused	2	(0.01)	2	(0.02)			
	1 = True	**156**	**(0.77)**	**93**	**(0.80)**	**63**	**(0.72)**	0.24
	2 = False	24	(0.12)	12	(0.10)	12	(0.14)	
	3 = Don't know	22	(0.11)	10	(0.09)	12	(0.14)	
Final total answered Q3 correctly:		1868	(0.97)	945	(0.98)	923	(0.97)	

Correct Answer in **bold;** p-value on "Answered correctly? (yes/no)"

Appendix F: Itemized Quiz Results

Quiz Item	Response	Overall (n=1916)		Simplified Form (n=969)		Traditional Form (n=947)		p-value
		n	%	n	%	n	%	
[QUIZ 4] The Biobank will ask me for some basic information about myself.	-1 = Refused	1	(0.00)	1	(0.00)			0.69
	1 = True	**1815**	**(0.95)**	**916**	**(0.95)**	**899**	**(0.95)**	
	2 = False	47	(0.03)	27	(0.03)	20	(0.02)	
	3 = Don't know	53	(0.03)	25	(0.03)	28	(0.03)	
[RE-QUIZ 4] I will not be asked to provide any information about myself to the Biobank.	-1 = Refused	3	(0.03)	2	(0.04)	1	(0.02)	0.84
	1 = True	20	(0.20)	11	(0.21)	9	(0.19)	
	2 = False	**60**	**(0.59)**	**32**	**(0.60)**	**28**	**(0.58)**	
	3 = Don't know	18	(0.18)	8	(0.15)	10	(0.21)	
Final total answered Q4 correctly:		1875	(0.98)	948	(0.98)	927	(0.98)	
[QUIZ 5] After getting some basic information from me, the Biobank will not contact me again.	-1 = Refused	0						0.00
	1 = True	315	(0.16)	185	(0.19)	130	(0.14)	
	2 = False	**1428**	**(0.75)**	**692**	**(0.71)**	**736**	**(0.78)**	
	3 = Don't know	173	(0.09)	92	(0.10)	81	(0.09)	
[RE-QUIZ 5] The Biobank will contact me to update my basic information.	-1 = Refused	3	(0.01)	2	(0.01)	1	(0.01)	0.34
	1 = True	**398**	**(0.82)**	**230**	**(0.83)**	**168**	**(0.80)**	
	2 = False	50	(0.10)	28	(0.10)	22	(0.10)	
	3 = Don't know	37	(0.08)	17	(0.06)	20	(0.10)	
Final total answered Q5 correctly:		1826	(0.95)	922	(0.95)	904	(0.95)	
[QUIZ 6] The Biobank will collect information from my medical records.	-1 = Refused	1	(0.00)		1.00	-0.10%		0.00
	1 = True	**1193**	**(0.62)**	**643**	**(0.66)**	**550**	**(0.58)**	
	2 = False	540	(0.28)	246	(0.25)	294	(0.31)	
	3 = Don't know	182	(0.10)	80	(0.08)	102	(0.11)	
[RE-QUIZ 6] The Biobank will not collect information from my medical records.	-1 = Refused	6	(0.01)	2	(0.01)	4	(0.01)	0.80
	1 = True	164	(0.23)	74	(0.23)	90	(0.23)	
	2 = False	**520**	**(0.72)**	**236**	**(0.72)**	**284**	**(0.72)**	
	3 = Don't know	33	(0.05)	14	(0.04)	19	(0.05)	
Final total answered Q6 correctly:		1713	(0.89)	879	(0.91)	834	(0.88)	

Correct Answer in **bold;** p-value on "Answered correctly? (yes/no)"

Appendix F: Itemized Quiz Results

Quiz Item	Response	Overall (n=1916)		Simplified Form (n=969)		Traditional Form (n=947)		p-value
		n	%	n	%	n	%	
[QUIZ 7] Unless I decide to stop taking part, my sample and information may be kept in the Biobank for an unlimited amount of time.	-1 = Refused	0						0.64
	1 = True	**1650**	**(0.86)**	**838**	**(0.87)**	**812**	**(0.86)**	
	2 = False	133	(0.07)	65	(0.07)	68	(0.07)	
	3 = Don't know	133	(0.07)	66	(0.07)	67	(0.07)	
[RE-QUIZ 7] My sample and information will not be kept in the Biobank for more than one year.	-1 = Refused	8	(0.03)	2	(0.02)	6	(0.04)	0.96
	1 = True	69	(0.26)	36	(0.28)	33	(0.24)	
	2 = False	**158**	**(0.59)**	**78**	**(0.60)**	**80**	**(0.59)**	
	3 = Don't know	31	(0.12)	15	(0.12)	16	(0.12)	
Final total answered Q7 correctly:		1808	(0.94)	916	(0.95)	892	(0.94)	
[QUIZ 8] Researchers may study my samples and information.	-1 = Refused	6	(0.00)	3	(0.00)	3	(0.00)	0.08
	1 = True	**1807**	**(0.94)**	**905**	**(0.93)**	**902**	**(0.95)**	
	2 = False	47	(0.03)	31	(0.03)	16	(0.02)	
	3 = Don't know	56	(0.03)	30	(0.03)	26	(0.03)	
[RE-QUIZ 8] My samples and information will not be used for research.	-1 = Refused	4	(0.04)	3	(0.05)	1	(0.02)	0.41
	1 = True	13	(0.12)	8	(0.13)	5	(0.11)	
	2 = False	**68**	**(0.62)**	**42**	**(0.66)**	**26**	**(0.58)**	
	3 = Don't know	24	(0.22)	11	(0.17)	13	(0.29)	
Final total answered Q8 correctly:		1875	(0.98)	947	(0.98)	928	(0.98)	
[QUIZ 9] Researchers will be able to easily identify me using the information they get from the Biobank.	-1 = Refused	8	(0.00)	4	(0.00)	4	(0.00)	0.55
	1 = True	283	(0.15)	143	(0.15)	140	(0.15)	
	2 = False	**1494**	**(0.78)**	**761**	**(0.79)**	**733**	**(0.77)**	
	3 = Don't know	131	(0.07)	61	(0.06)	70	(0.07)	
[RE-QUIZ 9] The Biobank will not give researchers information that directly identifies me.	-1 = Refused	6	(0.01)	5	(0.02)	1	(0.01)	0.06
	1 = True	**269**	**(0.64)**	**142**	**(0.68)**	**127**	**(0.59)**	
	2 = False	113	(0.27)	47	(0.23)	66	(0.31)	
	3 = Don't know	34	(0.08)	14	(0.07)	20	(0.09)	
Final total answered Q9 correctly:		1763	(0.92)	903	(0.93)	860	(0.91)	

Correct Answer in **bold;** p-value on "Answered correctly? (yes/no)"

Appendix F: Itemized Quiz Results

Quiz Item	Response	Overall (n=1916)		Simplified Form (n=969)		Traditional Form (n=947)		p-value
		n	%	n	%	n	%	
[QUIZ 10] Someone from the Biobank may contact me about participating in additional research.	-1 = Refused	4	(0.00)	3	(0.00)	1	(0.00)	0.19
	1 = True	**1547**	**(0.81)**	**771**	**(0.80)**	**776**	**(0.82)**	
	2 = False	203	(0.11)	106	(0.11)	97	(0.10)	
	3 = Don't know	162	(0.09)	89	(0.09)	73	(0.08)	
[RE-QUIZ 10] The Biobank will not contact me about participating in any additional research.	-1 = Refused	2	(0.01)	1	(0.01)	1	(0.01)	0.12
	1 = True	70	(0.19)	36	(0.18)	34	(0.20)	
	2 = False	**269**	**(0.73)**	**151**	**(0.76)**	**118**	**(0.69)**	
	3 = Don't know	28	(0.08)	10	(0.05)	18	(0.11)	
Final total answered Q10 correctly:		1816	(0.95)	922	(0.95)	894	(0.94)	
[QUIZ 11] None of my genetic or health information will ever be put into a database outside the Biobank.	-1 = Refused	4	(0.00)	2	(0.00)	2	(0.00)	0.00
	1 = True	822	(0.43)	442	(0.46)	380	(0.40)	
	2 = False	**891**	**(0.47)**	**409**	**(0.42)**	**482**	**(0.51)**	
	3 = Don't know	199	(0.10)	116	(0.12)	83	(0.09)	
[RE-QUIZ 11] Some of my genetic and health information might be put into a database outside the Biobank.	-1 = Refused	8	(0.01)	3	(0.01)	5	(0.01)	0.37
	1 = True	**873**	**(0.85)**	**482**	**(0.86)**	**391**	**(0.84)**	
	2 = False	100	(0.10)	54	(0.10)	46	(0.10)	
	3 = Don't know	44	(0.04)	21	(0.04)	23	(0.05)	
Final total answered Q11 correctly:		1764	(0.92)	891	(0.92)	873	(0.92)	
[QUIZ 12] Someone could easily trace information in a database outside the Biobank back to me.	-1 = Refused	8	(0.00)	4	(0.00)	4	(0.00)	0.73
	1 = True	157	(0.08)	78	(0.08)	79	(0.08)	
	2 = False	**1604**	**(0.84)**	**814**	**(0.84)**	**790**	**(0.83)**	
	3 = Don't know	147	(0.08)	73	(0.08)	74	(0.08)	
[RE-QUIZ 12] There is a small chance that someone could trace information in a database outside the Biobank back to me.	-1 = Refused	6	(0.02)	3	(0.02)	3	(0.02)	0.56
	1 = True	**233**	**(0.75)**	**118**	**(0.76)**	**115**	**(0.73)**	
	2 = False	44	(0.14)	19	(0.12)	25	(0.16)	
	3 = Don't know	29	(0.09)	15	(0.10)	14	(0.09)	
Final total answered Q12 correctly:		1837	(0.96)	932	(0.96)	905	(0.96)	

Correct Answer in **bold;** p-value on "Answered correctly? (yes/no)"

Appendix F: Itemized Quiz Results

Quiz Item	Response	Overall (n=1916)		Simplified Form (n=969)		Traditional Form (n=947)		p-value
		n	%	n	%	n	%	
[QUIZ 13] There is a risk that someone could get access to information the Biobank has about me.	-1 = Refused	4	(0.00)	3	(0.00)	1	(0.00)	0.41
	1 = True	**1368**	**(0.71)**	**700**	**(0.72)**	**668**	**(0.71)**	
	2 = False	394	(0.21)	186	(0.19)	208	(0.22)	
	3 = Don't know	150	(0.08)	80	(0.08)	70	(0.07)	
[RE-QUIZ 13] 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.	-1 = Refused	6	(0.01)	2	(0.01)	4	(0.01)	0.85
	1 = True	128	(0.23)	63	(0.23)	65	(0.23)	
	2 = False	**377**	**(0.69)**	**184**	**(0.68)**	**193**	**(0.69)**	
	3 = Don't know	37	(0.07)	20	(0.07)	17	(0.06)	
Final total answered Q13 correctly:		1745	(0.91)	884	(0.91)	861	(0.91)	
[QUIZ 14] The Biobank will take many steps to try to protect my privacy.	-1 = Refused	5	(0.00)	1	(0.00)	4	(0.00)	0.83
	1 = True	**1827**	**(0.95)**	**925**	**(0.96)**	**902**	**(0.95)**	
	2 = False	13	(0.01)	6	(0.01)	7	(0.01)	
	3 = Don't know	71	(0.04)	37	(0.04)	34	(0.04)	
[RE-QUIZ 14] There is nothing the Biobank will do to try to protect my privacy.	-1 = Refused	6	(0.07)	4	(0.09)	2	(0.04)	0.75
	1 = True	17	(0.19)	8	(0.18)	9	(0.20)	
	2 = False	**43**	**(0.48)**	**22**	**(0.50)**	**21**	**(0.47)**	
	3 = Don't know	23	(0.26)	10	(0.23)	13	(0.29)	
Final total answered Q14 correctly:		1870	(0.98)	947	(0.98)	923	(0.97)	
[QUIZ 15] Some types of discrimination based on my information are prohibited by law.	-1 = Refused	4	(0.00)	1	(0.00)	3	(0.00)	0.91
	1 = True	**1566**	**(0.82)**	**793**	**(0.82)**	**773**	**(0.82)**	
	2 = False	105	(0.06)	58	(0.06)	47	(0.05)	
	3 = Don't know	241	(0.13)	117	(0.12)	124	(0.13)	
[RE-QUIZ 15] There are no laws against discrimination based on my information.	-1 = Refused	5	(0.01)	3	(0.02)	2	(0.01)	0.20
	1 = True	102	(0.29)	49	(0.28)	53	(0.31)	
	2 = False	**203**	**(0.58)**	**108**	**(0.61)**	**95**	**(0.55)**	
	3 = Don't know	40	(0.11)	16	(0.09)	24	(0.14)	
Final total answered Q15 correctly:		1769	(0.92)	901	(0.93)	868	(0.92)	

Correct Answer in **bold;** p-value on "Answered correctly? (yes/no)"

Appendix F: Itemized Quiz Results

Quiz Item	Response	Overall (n=1916)		Simplified Form (n=969)		Traditional Form (n=947)		p-value
		n	%	n	%	n	%	
[QUIZ 16] Research done through the Biobank will provide me with personal health benefits.	-1 = Refused	8	(0.00)	5	(0.01)	3	(0.00)	0.48
	1 = True	272	(0.14)	123	(0.13)	149	(0.16)	
	2 = False	**1422**	**(0.74)**	**726**	**(0.75)**	**696**	**(0.74)**	
	3 = Don't know	214	(0.11)	115	(0.12)	99	(0.11)	
[RE-QUIZ 16] I should not expect to get personal health benefit from research done through the Biobank.	-1 = Refused	9	(0.02)	3	(0.01)	6	(0.02)	0.60
	1 = True	**349**	**(0.71)**	**169**	**(0.70)**	**180**	**(0.72)**	
	2 = False	91	(0.18)	53	(0.22)	38	(0.15)	
	3 = Don't know	45	(0.09)	18	(0.07)	27	(0.11)	
Final total answered Q16 correctly:		1771	(0.92)	895	(0.92)	876	(0.93)	
[QUIZ 17] If the research leads to any new products, I will get part of the profits.	-1 = Refused	6	(0.00)	3	(0.00)	3	(0.00)	0.53
	1 = True	79	(0.04)	43	(0.04)	36	(0.04)	
	2 = False	**1668**	**(0.87)**	**839**	**(0.87)**	**829**	**(0.88)**	
	3 = Don't know	163	(0.09)	84	(0.09)	79	(0.08)	
[RE-QUIZ 17] I will not get any profits if the research leads to any new products.	-1 = Refused	5	(0.02)	2	(0.02)	3	(0.03)	0.12
	1 = True	**147**	**(0.59)**	**83**	**(0.64)**	**64**	**(0.54)**	
	2 = False	65	(0.26)	32	(0.25)	33	(0.28)	
	3 = Don't know	31	(0.13)	13	(0.10)	18	(0.15)	
Final total answered Q17 correctly:		1815	(0.95)	922	(0.95)	893	(0.94)	
[QUIZ 18] I should not expect to get individual results back from research done using my sample.	-1 = Refused	7	(0.00)	1	(0.00)	6	(0.01)	0.09
	1 = True	**1602**	**(0.84)**	**824**	**(0.85)**	**778**	**(0.82)**	
	2 = False	156	(0.08)	63	(0.07)	93	(0.10)	
	3 = Don't know	151	(0.08)	81	(0.08)	70	(0.07)	
[RE-QUIZ 18] Researchers who are using my sample will provide me with individual results.	-1 = Refused	8	(0.03)	4	(0.03)	4	(0.02)	0.02
	1 = True	91	(0.29)	34	(0.23)	57	(0.34)	
	2 = False	**188**	**(0.60)**	**97**	**(0.67)**	**91**	**(0.54)**	
	3 = Don't know	27	(0.09)	10	(0.07)	17	(0.10)	
Final total answered Q18 correctly:		1790	(0.93)	921	(0.95)	869	(0.92)	

Correct Answer in **bold;** p-value on "Answered correctly? (yes/no)"

Appendix F: Itemized Quiz Results

Quiz Item	Response	Overall (n=1916)		Simplified Form (n=969)		Traditional Form (n=947)		p-value
		n	%	n	%	n	%	
[QUIZ 19] Once I sign up, I cannot leave the Biobank.	-1 = Refused	5	(0.00)	2	(0.00)	3	(0.00)	0.98
	1 = True	48	(0.03)	25	(0.03)	23	(0.02)	
	2 = False	**1764**	**(0.92)**	**892**	**(0.92)**	**872**	**(0.92)**	
	3 = Don't know	99	(0.05)	50	(0.05)	49	(0.05)	
[RE-QUIZ 19] I have the right to leave the Biobank.	-1 = Refused	4	(0.03)	1	(0.01)	3	(0.04)	0.10
	1 = True	**118**	**(0.78)**	**64**	**(0.83)**	**54**	**(0.72)**	
	2 = False	9	(0.06)	4	(0.05)	5	(0.07)	
	3 = Don't know	21	(0.14)	8	(0.10)	13	(0.17)	
Final total answered Q19 correctly:		1882	(0.98)	956	(0.99)	926	(0.98)	
[QUIZ 20] 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.	-1 = Refused	11	(0.01)	9	(0.01)	2	(0.00)	0.83
	1 = True	**1473**	**(0.77)**	**743**	**(0.77)**	**730**	**(0.77)**	
	2 = False	155	(0.08)	68	(0.07)	87	(0.09)	
	3 = Don't know	277	(0.15)	149	(0.15)	128	(0.14)	
[RE-QUIZ 20] 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.	-1 = Refused	7	(0.02)	3	(0.01)	4	(0.02)	0.87
	1 = True	118	(0.27)	64	(0.28)	54	(0.25)	
	2 = False	**278**	**(0.63)**	**141**	**(0.62)**	**137**	**(0.63)**	
	3 = Don't know	40	(0.09)	18	(0.08)	22	(0.10)	
Final total answered Q20 correctly:		1751	(0.91)	884	(0.91)	867	(0.92)	
[QUIZ 21] There is someone I can contact if I have questions or want more information.	-1 = Refused	6	(0.00)	1	(0.00)	5	(0.01)	0.39
	1 = True	**1806**	**(0.94)**	**909**	**(0.94)**	**897**	**(0.95)**	
	2 = False	19	(0.01)	11	(0.01)	8	(0.01)	
	3 = Don't know	85	(0.04)	48	(0.05)	37	(0.04)	
[RE-QUIZ 21] I will not be able to ask questions or get more information about the Biobank later.	-1 = Refused	5	(0.05)	2	(0.03)	3	(0.06)	0.58
	1 = True	27	(0.25)	18	(0.30)	9	(0.18)	
	2 = False	**56**	**(0.51)**	**32**	**(0.53)**	**24**	**(0.48)**	
	3 = Don't know	22	(0.20)	8	(0.13)	14	(0.28)	
Final total answered Q21 correctly:		1862	(0.97)	941	(0.97)	921	(0.97)	

Correct Answer in **bold;** p-value on "Answered correctly? (yes/no)"

Appendix G: Relationship between Willingness to Participate and Final Quiz Score