

**The Electronic Medical Records and Genomics (eMERGE) Network
Consent & Community Consultation Workgroup
Informed Consent Task Force**

MODEL CONSENT LANGUAGE

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This document represents the compiled work of eMERGE investigators and consultants on consent language for the collection and storage of human biospecimens and data for future research, particularly those collections that have an electronic medical records component. Portions of the language may also be useful for other genetic and genomic research, such as genome-wide association studies or candidate gene studies. The suitability of this language for whole genome sequencing is under evaluation.

To develop this language, the Informed Consent Task Force collected and compared existing consent language, including some that had been the subject of empirical research. With reference to existing best practice guidelines, we identified critical topic areas for the types of research outlined above and began developing model language to explain those essential elements. We focused closely on explaining concepts simply so that the language would be easy to read and understand. We revised the language through an iterative process involving extensive discussion by email and telephone over a period of approximately 1 year, as well as feedback from the larger Consent & Community Consultation Workgroup.

******* IMPORTANT NOTES *******

- Although this document roughly follows the order a consent form might take, it is not a continuous consent template. Rather, it contains discrete sections of text research teams can use as a starting point when creating their consent forms. Be sure to confirm that your final form contains all required elements and complies with your institution's requirements.
- The headings and subheadings are provided to aid research teams in identifying the content of different sections. They are not intended for use in the form itself.
- Some sections contain optional wording or alternate versions for use as appropriate, depending on the underlying policies and procedures for a particular study. Beyond these variations, however, ***it is very important that research teams customize all of the language to fit their studies.*** For example, under "Access to Biospecimens/Data"
 - The language describes many different kinds of researchers who could access stored materials—but your consent document should only list the kinds who will actually be allowed access your materials.
 - The language describes a scientific review process and an ethics review process—but your consent document should describe your particular review procedures.

These are only two examples from one section, but the general principle applies to every section. Be sure to read each one carefully and make any changes to ensure that it both **completely** and **accurately** describes your research.

- For sections that contain language about a procedure that may be optional (i.e., participants are given a choice), see the “Consent Statement” section at the end of this document for sample wording to present these choices.
- The reading statistics shown after each section are meant as a guide for the usefulness and potential applicability of the various sections to a particular population—and also as a reminder to try to keep your modifications simple!
- We expect this to be an evolving document. Send your comments and suggestions to Laura Beskow at laura.beskow@duke.edu.

BIOBANK PURPOSE

The purpose of this research project is to collect and store human samples (such as blood) and health information. Researchers can then use the stored materials in future studies. 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 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 samples and information. This collection is called the [name] (or just “the Biobank” in the rest of this form). The director of the Biobank is [name].

Passive Sentences	22%
Reading Ease (ideally 60-70; higher is better)	72.2
Grade Level (ideally 8 or below)	6.8

BLOOD DRAW

[Note: (1) Physical risks, and (2) Costs are covered in other sections.]

Short Version

We will draw about 3 tablespoons of blood from a vein in your arm.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	89.8
Grade Level (ideally 8 or below)	4.1

Longer Version (e.g., if the IRB requires that terms like “genes” and “DNA” be defined)

We will use a needle to draw 50 ml (about 3 tablespoons) of blood from a vein in your arm. 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.
- ‘RNA’ is short for ribonucleic acid. RNA delivers DNA’s genetic code to the part of a cell that makes proteins. RNA also helps control which genes are turned on or off at one point in time.

Passive Sentences	10%
Reading Ease (ideally 60-70; higher is better)	80.6
Grade Level (ideally 8 or below)	5.2

Residual Specimens

You are going to have blood drawn for medical tests your doctor ordered. He or she will give you the results of these tests and use them to plan your care. Even though the amount of blood drawn will only be what is needed for your care, there may still be some left over after all the tests are done. We would like to store this remaining blood in the Biobank.

Passive Sentences	25%
Reading Ease (ideally 60-70; higher is better)	86.3
Grade Level (ideally 8 or below)	5.6

COLLECTION OF INFORMATION

Basic Health Information

We will ask you for some basic information. This will include things like name, age, sex, and race or ethnic group. We will also ask about your family's health history. We will contact you no more than [frequency, e.g., once a year] to update this information.

- *If update contact is optional:* This will happen for as long as your sample is stored in the Biobank, unless you tell us not to. You can tell us now or in the future not to contact you.
- *If update contact is not optional:* This will happen for as long as your sample is stored in the Biobank.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	76.2
Grade Level (ideally 8 or below)	6.3

Clinical Information

We will collect information from your medical records at [institution]. Examples include results of tests, medical procedures, images (such as X-rays), and medicines you take. Researchers will use this information to better understand how genes affect health and response to treatment.

- *If medical record access is optional:* If you agree, we will look at your medical record from time to time to update this information. This will take place for as long as your sample is stored in the Biobank, unless you tell us not to. You can tell us now or in the future not to look at your medical record.
- *If medical record access is not optional:* We will look at your medical record from time to time to update this information. This will take place for as long as your sample is stored in the Biobank.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	61.3
Grade Level (ideally 8 or below)	9.0

Research Information

We will collect and store research data from studies done using your sample and information.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	56.2
Grade Level (ideally 8 or below)	9.1

DURATION OF STORAGE

There is no limit on the length of time we will store your sample and information. We may keep using them for research unless you decide to stop taking part or we close the Biobank.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	75.4
Grade Level (ideally 8 or below)	7.0

ACCESS TO BIOSPECIMENS/DATA

We will store your samples and information in the Biobank. Some of your genetic and health information might also be put into one more scientific databases.

Local Access [Note: This section describes the process by which researchers access materials stored in the Biobank; see also *Large-Scale Data Sharing*, which concerns sharing not under the direct control of the Biobank.]

Researchers can ask to study the materials stored in the Biobank. This includes researchers from [institution], 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.

A science committee at the Biobank will review each request. There will also be an ethics review. This kind of review is to make sure that any risks are minimized and that your rights and welfare are protected.

If a study is approved, we might give a part of your sample and information to the researchers, along with samples and information from many other people. We will not give researchers information that could directly identify you without your permission.

Passive Sentences	25%
Reading Ease (ideally 60-70; higher is better)	54.6
Grade Level (ideally 8 or below)	9.4

Large-Scale Data Sharing [Note: This section describes sharing that is not under the direct control of the Biobank, such as that required by NIH’s Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS).]

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease.

If you agree to take part 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 scientific databases; some are maintained by [institution], some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people.

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

Passive Sentences	23%
Reading Ease (ideally 60-70; higher is better)	47.8
Grade Level (ideally 8 or below)	10.9

RECONTACT

[Note: Recontact to update basic information is covered under “Collection of Information.”]

Additional Blood Sample

Over time, stored samples may be used up or decrease in quality.

- *If this contact is not optional:* We may contact you to ask for another blood sample.
- *If this contact is optional:* If you agree, we may contact you to ask for another blood sample. If you change your mind in the future, you can ask us not to contact you again.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	75.3
Grade Level (ideally 8 or below)	6.6

Additional Research

We will not notify you every time your sample and information are used. 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 Biobank will make initial contact:* If a study like this is approved, someone from the Biobank will contact you first. We will tell you about the study so you can decide if it is okay to give the researcher your name. If you agree, the researcher will then contact you to tell you more about the study.
- *If names will be given directly to researchers:* If a study like this is approved, the researcher will contact you to tell you more about the study.

There will be a new consent process just for that study. You can decide then to take part or not take part.

We will make sure researchers do not contact you about more than [limit, e.g., four] studies like this per year.

- *If this contact is optional:* It is up to you whether you want to allow us to contact you about future studies.

Passive Sentences	25%
Reading Ease (ideally 60-70; higher is better)	72.3
Grade Level (ideally 8 or below)	7.6

RISKS

[Note: Privacy protections are covered in the next section.]

Physical Risks

- *If blood is not drawn (i.e., specimen is leftover from clinical draw):* There are no physical risks to you.
- *If blood is drawn:* When we draw your blood, you may feel brief pain or have some bruising from the needle. Infection, light-headedness, and fainting are also possible, but unlikely.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	72.6
Grade Level (ideally 8 or below)	5.8

Privacy Risks

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. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. These efforts are described in the section below called “[section title].”

Passive Sentences	25%
Reading Ease (ideally 60-70; higher is better)	67.0
Grade Level (ideally 8 or below)	7.6

Group Risks

Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes.

Passive Sentences	25%
Reading Ease (ideally 60-70; higher is better)	66.8
Grade Level (ideally 8 or below)	8.5

PRIVACY PROTECTIONS

Federal privacy rules give safeguards for privacy, security, and authorized access. We will not give information that identifies you to anyone without your permission, except as required by law. This study takes many steps to protect the privacy of people who take part.

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. We will create a master list linking your code number to your name. We keep this list separate from your coded sample and information. Only study staff can access this list and they sign an agreement to keep your identity a secret.

We will keep the samples in locked freezers in locked buildings. We will keep health information and research data on secure computers. These computers have many levels of protection.

Research records are separate from medical records. We will not place any information from this study in your medical record.

Researchers who study your sample and information will not know who you are. We will give them only the 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.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	58.1
Grade Level (ideally 8 or below)	8.3

Genetic Information Nondiscrimination Act

There is a new Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	26.2
Grade Level (ideally 8 or below)	14.4

Certificates of Confidentiality

To help protect your privacy, the Biobank has a Certificate of Confidentiality from the government. The Certificate says that the Biobank does not have to give out your personal information, even if ordered to by a judge or court.

There are still a few times when we will need to share your personal information:

- The government will still be able to get the information it needs to manage projects that use federal money.
- *Optional – customize according to the terms of your Certificate:* State law says we must report:
 - cases of diseases that spread easily,
 - abusive behavior (toward a child, a partner, or an elderly person), and
 - people who say they are going to hurt themselves or someone else.

The Certificate only applies to the Biobank. You can still give out information about yourself.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	54.1
Grade Level (ideally 8 or below)	9.2

BENEFITS

You should not expect to get direct health benefits from this research. The main reason you may want to take part is to help researchers find new ways to prevent, detect, and treat health problems in the future.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	76.2
Grade Level (ideally 8 or below)	7.3

COSTS & PAYMENTS

There are no costs to you or your insurance for taking part in the Biobank. If your doctor ordered a blood draw for your medical care, we can collect blood for the Biobank at the same time to reduce the number of needle sticks you have. In that case, your insurance will be billed for the blood draw your doctor ordered.

- *If no payment:* We will not pay you for taking part in the Biobank.
- *If payment:* We will give you [incentive, e.g., a \$25 gift card] for the time it takes to join the Biobank.

Passive Sentences	20%
Reading Ease (ideally 60-70; higher is better)	77.1
Grade Level (ideally 8 or below)	7.2

COMMERCIALIZATION

We will use your sample only for research. We will not sell it. However, research results might someday lead to the development of a medical or genetic test, drug, or other commercial product. You will not receive money from the sale of any such product.

- *If no benefit to institution:* [Institution] employees will also not receive money. [Institution] will use any money it makes from the sale of such products for [fill in as appropriate, e.g., for research and non-profit public benefit purposes within your institution].
- *If possible benefit to institution:* Researchers, [institution], and/or others may own these products and make money by selling them.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	47.8
Grade Level (ideally 8 or below)	10.3

RETURN OF RESULTS

Individual Results

You should not expect to get individual results from research done through the Biobank. Researchers must study samples and information from many people over many years before they can know if the results have meaning. We will not give the results to your doctor. We will not put them 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. If this happens, we will contact you to see if you want to learn more.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	69.6
Grade Level (ideally 8 or below)	7.3

Aggregate Results

We will send a newsletter [frequency, *e.g.*, “once a year”] to people who take part in the Biobank. The newsletter will give general updates about the studies being done. You can also get general news about the studies at [URL].

Passive Sentences	33%
Reading Ease (ideally 60-70; higher is better)	68.5
Grade Level (ideally 8 or below)	7.0

WITHDRAWAL

You have the right to leave the project any time. If you want to leave the project, call the Biobank at [phone number] to let us know. We will send you a form with several options so you can tell us what to do with your unused sample. [*]

Please note:

- You cannot withdraw your samples and information from studies that have already begun.
- We cannot get back samples or information that we have already given out to researchers.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	72.2
Grade Level (ideally 8 or below)	6.9

Optional – insert above at [*]: These options are:

- No more contact. This means we would no longer contact you to update your personal information or to ask you to take part in more research. But we would still have your okay to keep and use the sample and information we already have. We would still have your okay to use your medical record to get updated information about your health.
- No further access. This means we would no longer contact you or get updated information from your medical record. But we would still have your okay to keep and use the sample and information we already have.
- Unlink. This means we would forever remove the link between the code number and your name. We would still have your okay to keep and use the sample and information we already have, but we would have no way to know that they are yours. We would also have no way to contact you or use your medical record.
- No further use. This means we would destroy any part of your sample left in the Biobank and no longer use or update your personal medical information.

Passive Sentences	0%
Reading Ease (ideally 60-70; higher is better)	71.6
Grade Level (ideally 8 or below)	6.7

CONSENT STATEMENT

[Note: Be sure to customize the numbered list below based on which parts (if any) of your research are optional.]

The project staff has explained to me the purpose of the Biobank, the procedures involved, and the risks and benefits. I have asked all the questions I have now, and I know who to contact if I have more questions.

I voluntarily agree that my blood and information can be stored at the Biobank. I understand it may be used in future research to learn about, prevent, or treat health problems.

In addition, I have made the optional choices marked below. I know that I can still take part in the Biobank, even if I answer 'no' to any of these options.

1. Someone from the Biobank can contact me once a year to update my basic information.

YES _____ (initials) NO _____ (initials)

2. Someone from the Biobank can use my medical record from time to time to get updated information about my health.

YES _____ (initials) NO _____ (initials)

3. Someone from the Biobank can contact me to ask for another blood sample.

YES _____ (initials) NO _____ (initials)

4. Someone from the Biobank can contact me about offers to take part in more research.

[OR: Researchers can contact me about offers to take part in more research.]

YES _____ (initials) NO _____ (initials)

5. I would like to receive the Biobank's newsletter.

YES _____ (initials) NO _____ (initials)

Passive Sentences	8%
Reading Ease (ideally 60-70; higher is better)	63.6
Grade Level (ideally 8 or below)	8.3