Checklist for Reviewing Studies Involving Genetic Biobanking

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Biobanking System

Depiction of primary researchers, biobank, and secondary researchers—a biobank research system. As noted in text, collection of data and samples from contributors may occur at Stage 1 research and collection sites or at Stage 2, the biobank itself.
Genetic Biobanking

- Collection of DNA
  - Often from blood or buccal swab
  - Specifically for biobanking
  - Remaining sample

- Health information
  - Collected at time sample is obtained
  - Medical Records
  - Periodic updates

- Lifestyle information

- Family history information
Consenting

• Can consent for broad use of samples
• Can be ongoing (dynamic)
• Can give tiered consent

I agree my specimens may be kept for use in future research to learn about, prevent, treat or cure cancer.

I do not agree my specimens may be kept for use in future research to learn about, prevent, treat or cure cancer.

I agree my specimens may be kept for use in research about other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).

I do not agree my specimens may be kept for use in research about other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).

I agree someone may contact me in the future to ask me to allow other uses of my specimens.

I do not agree someone may contact me in the future to ask me to allow other uses of my specimens.
Genetic Biobanking: Protocol & Informed Consent

• Needs to Address the following topics:
  – Purpose
  – Definitions
  – Storage
  – Access to biospecimens/data
  – Recontact
  – Data sharing
  – Confidentiality
  – Return of results
  – Laws protecting genetic information (e.g. GINA & ACA)
  – Certificate of Confidentiality (optional)
  – Discontinuing participation
Checklist

Purpose:
☐ Explain what type of future research the samples will be used for (e.g., the purpose of the biobank: to provide samples for research in a specific disease(s), research related to the condition of the main study, and/or different purposes)
☐ Define terms such as DNA, genetic variant, biomarker, gene, etc.

Storage of Samples and Data:
☐ Where will the samples be stored? (With the sponsor? At Northwestern? Other?)
☐ How long will the samples be stored?
☐ Types of samples to be stored (e.g., DNA RNA, etc.)
☐ Will specific genetic information be stored? (e.g., results of genetic testing/research performed on the sample)

Privacy and Confidentiality:
☐ Will samples be identified, coded, or de-identified
☐ How will information associated with the sample be protected at storage location? (e.g., secure database, firewalls, limited access, etc.)
☐ If PHI is stored, ensure study is compliant with Northwestern’s Data Security Plan for Identifiable Information Used in Clinical Research (http://www.feinberg.northwestern.edu/docs/Data_Security_Plans_for_Identifiable Information_Used_in_Clinical_Research_9_1_14.pdf)
☐ What health information will be stored associated with the samples? (e.g., diagnosis codes, diagnosis, chart notes, dates of service, name, age, lab results, etc.)
☐ Will there be ongoing collection of health information on participants to associate with samples? (e.g., either by recontacting participant or via the medical record)
☐ If samples are used by other researchers not a part of the current study (secondary use of samples):
  ☐ How will the samples be identified? (Will they still be coded, de-identified, or have any PHI associated with them?)
  ☐ What other information will be associated with the sample?
☐ Is there a Certificate of Confidentiality?
☐ Mention of laws protecting participants from health insurance discrimination based on their genetic information (GINA, Affordable Care Act)

Risks:
☐ Mention that there is always a risk (small) of being identified due to the uniqueness of DNA

May 22, 2015
Model Language: Definitions

- **Genes** are pieces of DNA that contain the instructions for how our bodies grow and work. The DNA is what stores these instructions. **DNA** is inherited from your parents and can be passed on to your children.
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Risks:
- Mention that there is always a risk (small) of being identified due to the uniqueness of DNA
Blood samples stored for future research
Allowing for the storage and future testing of your blood samples will involve no cost to you. Your samples will be used only for research and will not be sold. The research done with your blood samples may lead to the development of new products in the future. No compensation will be given to you now or in the future for the use of these samples.

Consent Form for Use of Specimens for Research

About Using Specimens for Research

We would like to use these specimens for future research. If you agree, these specimens will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How are Specimens Used for Research" to learn more about specimen research.
**What is the reason for doing this sub-study?**
The purpose of this optional sample donation is to better understand why certain patients are more likely to respond to treatment than others. This will help in the development of personalized medicines, which means getting the right medicine to the right patient. To achieve this goal, the study sponsor would like to collect samples of your blood for storage and future research, including genetic testing.
The samples in the clinical repository may be used to help researchers to:

- Better understand how [study drug] (a study drug in the main study) works in the treatment of patients with [disease X] and to better predict which patients are more likely to respond to medicines such as [medication].
- Better understand how and why [disease X] and autoimmune-related diseases act differently in different people.
- Develop new treatments for [disease X] or autoimmune-related diseases.
- Find reasons why certain people are more likely to have side effects to medicines such as [medication].
- Find out how medicines such as [medication] are processed by people's bodies and how such treatment may affect people's bodies.
- Develop better ways for preventing diseases or treating diseases earlier.
- Develop or improve tests that help with detection or understanding of [disease X] and autoimmune-related diseases, to help identify the right medicine for the right patient.

Results from this research will be based on information from all of the patients who contribute samples.
Checklist

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- Define terms such as DNA, genetic variant, biomarker, gene, etc.

Storage of Samples and Data:
- Where will the samples be stored? (With the sponsor? At Northwestern? Other?)
- How long will the samples be stored?
- Types of samples to be stored (e.g., DNA, RNA, etc.)
- Will specific genetic information be stored? (e.g., results of genetic testing/research performed on the sample)

Privacy and Confidentiality:
- Will samples be identified, coded, or de-identified?
- How will information associated with the sample be protected at storage location? (e.g., secure database, firewalls, limited access, etc.)
- If PHI is stored, ensure study is compliant with Northwestern’s Data Security Plan for Identifiable Information Used in Clinical Research (http://www.feinberg.northwestern.edu/docs/Data_Security_Plans_for_Identifiable_Information_Used_in_Clinical_Research_9_1_14.pdf)
- What health information will be stored/associated with the samples? (e.g., diagnosis codes, diagnosis, chart notes, dates of service, name, age, lab results, etc.)
- Will there be ongoing collection of health information on participants to associate with samples? (e.g., either by recontacting participant or via the medical record)
- If samples are used by other researchers not a part of the current study (secondary use of samples):
  - How will the samples be identified? (will they still be coded, de-identified, or have any PHI associated with them?)
  - What other information will be associated with the sample?
- Is there a Certificate of Confidentiality?
- Mention of laws protecting participants from health insurance discrimination based on their genetic information (GINA, Affordable Care Act)

Risks:
- Mention that there is always a risk (small) of being identified due to the uniqueness of DNA
De-identified vs. Coded

- De-identification:

**Figure 1.** Two methods to achieve de-identification in accordance with the HIPAA Privacy Rule.
De-identified vs. Coded

- **Coded Information:**
  - Any identifying information that could allow the investigator to link a participant with his/her specimen or information
  - When a key to decipher the code exists

- **Limited data set:**
  - Almost “de-identified”
• There is a risk that someone could trace the information stored back to you. Even without your name or other identifiers, your genetic information is unique to you (like a fingerprint). While the chance for this to happen is very small, it is possible that this risk may grow in the future if people come up with new ways of tracing information.
Confidentiality-Example

Things to Think About

The choice to let us keep the left over specimens for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your specimens can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your specimens. Then any specimens that remain will no longer be used for research.

In the future, people who do research may need to know more about your health. While [redacted] may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if your specimens are used for this kind of research, the results will not be put in your health records.

If your confidential genetic information is discovered, you may suffer from genetic discrimination. Genetic discrimination occurs if people are treated unfairly because of differences in their genes that increase their chances of getting a certain disease. In the past, this could have resulted in the loss of health insurance or employment. Because of this, The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, was passed by Congress to protect Americans from such discrimination. The new law prevents discrimination from health insurers and employers. This act was signed into federal law on May 21, 2008, and went into effect May 2009. This law does not cover life insurance, disability insurance and long-term care insurance.
Return of Results:

☐ Does the PI intend to return results from research using the stored samples?

   If NO:
   ☐ Need to specifically state that results will not be returned to participant or their physician(s)

   If YES, need to address the following issues:
   ☐ How will it be determined which results will be returned?
   ☐ Which results will be returned (primary or secondary)?
     Secondary results are results that are not related to the initial intent of the main study (e.g., giving results about risk for heart disease when the focus of the study was pancreatic cancer)
   ☐ If secondary results to be returned, which ones?
     If Yes, the criteria for how that determination is made needs to be described
   ☐ Results validated in a CLIA laboratory (if not already performed in one)?
   ☐ Who will receive results (doctor and/or patient)?
   ☐ How will they receive results?
   ☐ Will they be placed in the participants’ medical records?
   ☐ Is support available (e.g., genetic counseling) either by referral or by study team member?
   ☐ How long will results be curated (to check for changes in interpretation)?
   ☐ How will any change in interpretation of results be communicated?

Data Sharing and Secondary Use of Samples:

☐ Will samples be used by researchers not part of current study?
☐ How will permission for these researchers be granted? (will researchers need to have some type of prior approval e.g., IRB, PIs, or Sample Access Committee?)
☐ Is Biobank using NIH funding?
  ☐ If YES, needs to comply with NIH Genomic Data Sharing Policy (deposing de-identified data into the relevant NIH-designated data repository via dbGaP: http://odc.nih.gov/PDF/NIH_GDS_Policy.pdf)
☐ Will data be shared with any other organization? (e.g., outside of NU, commercial entities, international organizations?)
☐ If genetic information is being stored, will that information be shared with any other organization? (e.g., outside of NU, commercial entities, international organizations?)

Recontact (If protocol & consent form offer this option)

☐ What is the purpose of re-contacting participants? (e.g., to obtain additional information, to obtain additional samples, to offer them opportunities to participate in further research, etc.)
☐ How often will participants be recontacted?
☐ Who will recontact participants?
Model Language: Data Sharing

- We may place some of your sample, genetic information, and health information in scientific databanks along with that from many other people. Information that could directly identify you will never be included. Researchers who want to study the information must apply to use the databank.
Optional Study Elements:

You would like to use your study data, where a code replaces your name, and your remaining coded biological samples including blood and tumor samples for additional medical and/or scientific research projects that are outside of the current study purpose and objectives. These research projects may relate to basal cell carcinoma and associated potential medicines. This may include research to help develop ways to detect, monitor or treat basal cell carcinoma.

Some of the projects may be carried out by researchers other than your Study Doctor. These researchers may be based in countries other than your own where data protection laws may not be equal to your own country. Researchers will be bound by agreements that restrict their use of the data, including its disclosure to anyone else. Site monitors, auditors, ethics committees and/or regulatory authorities may also need to access your data in connection with such additional research. Your data will be retained as long as it is useful for such purposes. If the results of such studies are published or presented in a meeting, your identity will not be disclosed.

The biological samples will be labeled with a unique code and be stored under [Redacted]'s control for a maximum of 15 years (some samples may be stored for much less time). During and after the study, you have the right to have any remaining sample material destroyed by [Redacted] (the Sponsor) at any time. If you choose to have your samples destroyed, please contact your Study Doctor. [Redacted] is responsible for the destruction of these samples at the end of the storage period. Any data generated from the additional research studies will belong to [Redacted] and will not become part of your medical record.

You do not have to agree to these uses of your study data and biological samples for additional research. If you choose to take part, you can change your mind at any time. Your decision to refuse the use of your study data and biological samples for additional use will in no way impact your participation in the study.
Consent Form Examples

**Genetic Research:**
Genetic tests study an individual’s inherited characteristics, found in DNA, which is present in each of the cells of your body. DNA contains information needed to construct and operate a human body. The blood samples collected may be used for genetic studies, if you choose to give us permission to do so. Donation of blood, urine, and/or biopsy for these particular research purposes is optional and you can still participate in this study if you do not want these genetic tests to be done on your samples. Donation of blood and/or urine for this reason is not genetic testing.

The results:
1. Will not be told to you.
2. Will not be put in your health records.
3. Will only be used for research.
4. Will not be sold.

The research done with your sample may help to develop new products in the future, but you will not be compensated for any future findings. Specific results of genetic testing being performed as a part of this study are not likely to affect you.

Your sample:
1. Will be identified by a code.
2. Will not contain any personal identifiers such as your name, social security number, address, phone number, or medical record number.
3. Will not be used for genetic cloning, paternity testing, or other personal identification.

We will make all attempts to protect your personal information. DNA, like your fingerprint, is unique to you and because of this there is a rare possibility that you can be identified by this sample.
Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part, a sample of tissue from your previous biopsy and some of your blood will be collected. The researchers ask your permission to store and use your samples and health information for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called “biobanking”. The Biobank is being run by the [Redacted] and supported by the National Cancer Institute.
WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1. About 2-3 tablespoons of blood will be collected from a vein in your arm at the same time that other blood is drawn (at week 4 of chemotherapy and radiation therapy, and at 4 and 12 months after you finish chemotherapy and radiation therapy) and a sample from the tissue that was collected in a prior biopsy will be sent to the Biobank.
2. Your sample and some related information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up.
3. Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
4. Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5. Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.
WHAT ARE THE POSSIBLE RISKS?

1. The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2. There is a risk that someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone may be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
3. There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. Research results will not be returned to you or your doctor.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, life insurance companies may charge a higher rate based on this information.

Some states have laws to protect against genetic discrimination. A federal law called the Genetic Information Non-Discrimination Act, or GINA, is in effect. This law does not allow discrimination by insurers or employers. The law does not include other types of misuse by life insurance, disability, or long term care insurance. To learn more about the GINA Law, please ask your study doctor.
HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?
Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1. When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.

2. The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and the ____________________________ staff with access to the list must sign an agreement to keep your identity confidential.

3. Researchers to whom the ____________________________ sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.

4. Information that identifies you will not be given to anyone, unless required by law.

5. If research results are published, your name and other personal information will not be used.
Additional Resources


Pharmacogenetic Testing

- Not all medicines work for all people and not all people have the same good or bad effects from a medicine. This is because a person’s genes affect the way they respond to drugs. The study of how genes affects the way they respond to drugs is called pharmacogenetics. This study involves pharmacogenetic testing to see if there are any genes that would affect how the study drug will work. [Describe the amount of blood to be withdrawn and at what time points; or tissues to be obtained]
NU Template Language

- Genetic Research
  - Researchers want to learn about the role of genes (or inherited traits) in health and disease. Genetic research may discover genes, find out how genes work, or help researchers learn how to use what we know about genes to treat or prevent disease.
• **Risks from Genetic Research**
  - Disease testing and genetic research may produce results about your medical condition. One question for you to consider is whether you should know the results of the testing and research. Knowing the results has risks. The results may cause you anxiety and other psychological distress. Also, if you tell the results to your doctor, they may become part of your medical record. If released, the information could lead to health or life insurance discrimination, job or social discrimination. Knowing the results could also affect your future relationships with family members.

  - **If applicable add:** Because your family members are also part of this study, there is a risk that the results may show that some are your family members are not genetic relatives. There is also a risk that other family members may learn private genetic information about you.) Not knowing results also has risks. It could mean that you will not have enough information regarding the need for treatment or the availability of a cure for a particular disease.
In order to speed research, it is often helpful for researchers to share the genetic information they get from studying blood or tissue samples. Other researchers can then compare that information to the genetic information from people in other studies. This type of genetic research is called Genome Wide Association Testing (GWAS). By sharing information, researchers can learn even more about human health and disease. If you agree, some of your genetic and health information may be released into one or more scientific databases. There are many scientific databases where your information may go. Some are kept by Northwestern, some are kept by the National Institutes of Health, and some are kept by private companies. Some of these databases can be used by the public. Others are restricted and can only be used by approved researchers. Your name and other information that could identify you will never be released into a scientific database. Nobody will know just from looking at a database that the information belongs to you.

___ I agree to have my de-identified information placed in a repository for any future research or share it with other researchers.

___ I do not agree to have my de-identified information placed in a GWAS repository for any future research or share it with other researchers.