Template Informed Consent Document for Biospecimen Banking

Drafted by Kristen Rosati
Coppersmith Brockelman PLC
for discussion by the Arizona Biospecimen Consortium*
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Background Information for Implementation of Template Informed Consent Document

Regulatory Requirements for Informed Consent: Federal regulations impose the following requirements for informed consent documents:

- Language that is understandable to the participant or the representative who will be signing the document;
- No boilerplate language that may be irrelevant to the research;
- No prohibited exculpatory language;
- A statement that the study involves research, an explanation of the purposes of the research, and an explanation of the expected duration of the participation. In a biospecimen banking informed consent, the "research" is the biobank and an explanation of what types of research may be conducted with the biospecimens;
- A description of the procedures to be followed, and identification of any procedures that are experimental. In a biospecimen banking informed consent, this would be the procedures for collecting, maintaining, and distributing the biospecimens for research (but would not include any experimental procedures);
- A description of reasonably foreseeable risks or discomforts to the participant. In a biospecimen banking informed consent, this would encompass any risks or discomforts in the process of collecting the biospecimens, as well as the privacy risks to the participants.
- A description of benefits to the participant or to others which may reasonably be expected from the research;
- A statement describing how records identifying the participant will be maintained confidentially;
- Information on whom to contact in the event of a research-related injury. In a biospecimen banking informed consent, this primary involves a contact for privacy-related concerns.
- Information on whom to contact for answers to pertinent questions about the research and research participants' rights;
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;
- If applicable, an explanation of the circumstances under which the participant's

* This Template Informed Consent Document for Biospecimen Banking is for educational purposes and is not intended to be legal advice. Please consult your legal counsel for questions concerning your particular circumstances. Kristen acknowledges the assistance of Naomi Jorgensen, Coppersmith Brockelman PLC, in preparing this document.

participation may be terminated by the investigator without regard to the participant's consent;

- An explanation of the consequences of a participant's decision to withdraw from the research and procedures for termination of participation by the participant;
- Where appropriate, an explanation of the approximate number of participants involved in the study;
- The participant's signature and date of signature; and
- If the authorization is executed by a personal representative of the participant (the participant's health care decision maker, such as parent consenting on behalf of a child), a description of that person's authority to act for the participant; and
- The signature of the person obtaining the consent of the participant or the personal representative, and the signature of the translator (if applicable).

There are other regulatory requirements for informed consent that generally are not applicable in the biorepository context, including:

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- If the research involves more than minimal risk, an explanation about compensation or medical treatments available if injury occurs or where further information may be obtained;
- If applicable, a statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;
- A description of any additional costs to the participant that may result from participation in the research (not likely applicable in a biospecimen banking protocol); and
- Where appropriate, a statement that significant new findings developed during the course of the research will be provided to the participant if they relate to the participant's willingness to continue participation.

If the informed consent also serves as a HIPAA authorization, the informed consent also must include:

- A specific and meaningful description of the protected health information ("PHI") to be used or disclosed in the research;
- The name or specific identification of the persons or class of persons authorized to make the disclosure;
- The name or specific identification of the persons or class of persons who will have access to the PHI;
- A description of the specific research protocol or study (which for a biorepository is the protocol for how the biospecimens are collected, maintained, and distributed);
- An expiration date or event, or a statement that the authorization has no expiration;
- A statement of the participant's right to revoke the authorization in writing and a description of how to do so;
- A statement that the participant may not revoke the authorization as to PHI already disclosed for research where the PHI is necessary to maintain the integrity of the study data, or a description of other exceptions where the participant may not revoke the

authorization;

- A statement that the entity disclosing the PHI may not condition treatment, payment, enrollment, or eligibility for benefits on the participant signing the authorization;
- A statement that the information disclosed for the research may be subject to redisclosure by the recipient and no longer be protected by the federal privacy rule (if that is accurate); and
- If the participant will not be given access to medical records during the study, a statement that the participant agrees to the denial of access when consenting to participate in the study, and that the right of access to the records will be reinstated upon completion of the study (although this generally will not be applicable in a biorepository protocol).

NIH Requirements for Informed Consent for Genomic Data Sharing: The National Institutes of Health Genomic Data Sharing Policy (the "GDS Policy") requires informed consent for use of de-identified biospecimens for certain genetic research. The policy applies to all "NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies, single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data.[1] The GDS Policy applies only to:

- Competing grant applications submitted to NIH on or after January 25, 2015;
- Proposals for contracts submitted to NIH on or after January 25, 2015; and
- NIH intramural research projects generating genomic data on or after January 25, 2015.

The Notice of the Implementation of the GDS Policy provides further clarification of the application of the policy to research conducted pursuant to contracts or awards before the effective date:

> Although the GDS Policy does not apply to research submitted prior to the Policy's effective date, NIH, nonetheless, strongly encourages investigators to comply with the expectations outlined in the Policy. Investigators should provide an updated genomic data sharing plan to the funding IC in the submission of the research performance progress report. For studies involving human participants that were initiated before the Policy's effective date and used consents that do not meet the expectations of the GDS Policy, investigators are expected to plan to transition to a consent for future research uses and broad sharing, if possible, particularly for new or additional collections of specimens. There will be reasonable accommodation, determined on a case-by-case basis by the funding IC, for long-term projects ongoing at the time of the Policy's effective date to come into alignment with NIH's expectations for consent and data sharing. The goal is to bring these projects into alignment, to the extent possible, in a reasonable timeframe.[2]

Suggested Best Practices for Informed Consent for Biospecimen Banking: Best practices in the industry indicate that an informed consent to contribute biospecimens to a biobank should include:

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[1] *See* http://gds.nih.gov/PDF/NIH_GDS_Policy.pdf, published Aug. 28, 2014.
[2] http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-111.html

- A clear description of the operation of the repository, including whether identifiable information will be maintained in the repository and how identifiable information will be linked to the specimens (if applicable);
- A description of whether research results will be linked to the biospecimens;
- The conditions under which data and specimens will be released to recipient-investigators;
- Procedures for protecting the privacy of human subjects and confidentiality of data;
- Specific descriptions of the nature and purpose of the research; and
- Where genetic research is anticipated, information about the risks of genetic research.

Confidentiality: An informed consent document "should state whether identifiable or coded information will be maintained in the biospecimen resource and if research results will be linked to other data about the human research participant, such as clinical data . . . . If longitudinal data will be collected by accessing the participant's medical records, the informed consent document should clearly state this. The informed consent document also should describe whether the biospecimens and/or the data associated with or derived from biospecimens will be shared with other investigators and, if so, the oversight mechanisms for such sharing."[3]

Genetic research: An informed consent document must discuss any reasonably foreseeable risks to participating in research.[4] If the biospecimens contributed to a research repository could be used for genetic research (which is likely), the informed consent document should expressly address the risks of accidental release of genetic information.

The passage of the Genetic Information Nondiscrimination Act of 2008 ("GINA")[5] has decreased the risks of genetic testing in research. GINA prohibits discrimination based on genetic information in health insurance and employment, but does not protect against discrimination in life insurance, disability insurance, or long-term care insurance. In addition, GINA does not apply to employers with fewer than 15 employees.[6] GINA protects "genetic information," which includes the information derived from an individual's genetic testing, but also protects information about an individual's family history ("the manifestation of a disease or disorder in family members"), genetic testing of an individual's family members, an individual's or his family members' request for or receipt of genetic services (testing, counseling or education) or participation in clinical research involving genetic services.[7] For additional details regarding the provisions of GINA, see the NIH, National Human Genome Research Institute

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[3] *See* National Cancer Institute's Best Practices for Biospecimen Resources (2011), http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf, at C.2.3.2.
[4] 45 C.F.R. § 46.116(a)(2).
[5] Public Law 110-233 (110th Cong. 2008), 122 Stat. 881, c*odified at* 42 U.S.C. § 2000ff note; *see also* 45 C.F.R. § 160.103. For additional details regarding the provisions of GINA see http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf.
[6] *See* http://www.hhs.gov/ohrp/humanparticipants/guidance/gina.html#fn.
[7] U.S.C. § 2000ff, *et al* DOL, FAQs of the Genetic Information Nondiscrimination Act, http://www.dol.gov/ebsa/faqs/faq-GINA.html.

Web site,[8] OHRP guidance on GINA,[9] and the National Cancer Institute ("NCI") guidance on GINA. [10]

The NCI published a template informed consent document for research,[11] in which NCI suggests addressing privacy risks as follows: "The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small." However, the NCI language does not provide information about the potential *effect* of the release of information, which we recommend to communicate risk to individuals.

In the OHRP guidance document entitled, "Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards,"[12] the OHRP noted the limitations of GINA, and urged Investigators and IRBs not to overstate the protections provided. OHRP suggested the following language for consideration by IRBs:

> A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
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> - Health insurance companies and group health plans may not request your genetic information that we get 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 that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
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> Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or longterm care insurance.

In addition, OHRP noted that, "for research that involves determining whether participants have an already manifest genetic disease or disorder, investigators and IRBs may wish to consider including additional language in the informed consent document indicating that GINA does not prohibit discrimination on the basis of an already manifest genetic disease or

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[8] *See* The Genetic Information Nondiscrimination Act of 2008, Information for Researchers and Health Care Professionals (April 6, 2009), at http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf.
[9] *See* OHRP Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (Mar. 24, 2009) at http://www.hhs.gov/ohrp/humansubjects/guidance/gina.pdf.
[10] *See* National Cancer Institute's Best Practices for Biospecimen Resources (2011), http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf, at C.2.3.5.
[11] The NCI Cancer Diagnosis Program's model tissue consent form can be found at http://www.cancerdiagnosis.nci.nih.gov/specimens/model.pdf.
[12] http://www.hhs.gov/ohrp/humanparticipants/guidance/gina.html.

disorder."[13]

Alternative language to consider:

> [Insert holder of biospecimen bank] has extensive precautions in place to prevent any unauthorized disclosure of personally identifiable information. However, if there is an accidental disclosure of information that can be used to identify you, it could affect your insurability, employment, family relationships or other legal rights. You should know that there are measures in place to prevent this from taking place. State and federal law, such as the Genetic Information Nondiscrimination Act (GINA), prohibit health insurance companies and larger employers from discriminating against people based on their genetics. There may be unforeseeable risks that are not known at this time. However, you will be informed of any new risks as they become known.

Exculpatory language: An informed consent form cannot include exculpatory language, which waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence.[14]

Description of commercial use of biospecimens: In the National Cancer Institute's Best Practices for Biospecimen Resources (2011), the NCI states that the informed consent document "should address the use of biospecimens and/or data by private or for-profit entities and the possibility of research leading to future development of commercial products, as appropriate. The document should describe whether human research participants, their families, or communities will receive any financial or nonfinancial benefits from the products, tests, or discoveries resulting from the research."[15]

Access to research results: An informed consent document should address the issue of whether the participant will have access to the research results, and whether the participant will be contacted with any clinically significant findings.[16] If the biospecimens are anonymized (de- identified before submission to the repository and not linked by code to identifying information) recontacting the participants is not possible. Moreover, even if the biorepository maintains a link, the institution that maintains the biorepository will not always perform the research, and requiring the recipients of biospecimens to communicate results back to the biorepository for communication to the donors would be difficult to manage. In addition, it is difficult to determine in the research context whether research findings are clinically relevant to an individual and there is often a small likelihood that statistically valid results will be available during the course of an individual's disease progression; premature communication of research results may pose a clinical risk to the participant. Because of these difficulties, many informed consent documents for biospecimen banking take the approach that the participants will not be informed of the specific research results.

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[13] *Id*.
[14] 45 C.F.R. § 46.116.
[15] *See* National Cancer Institute's Best Practices for Biospecimen Resources (2011), http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf, at C.2.3.6.
[16] *See* National Cancer Institute's Best Practices for Biospecimen Resources (2011), http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf, at C.2.3.7.

Withdrawal from participation in the biospecimen bank: Generally, a biorepository consent will inform an individual that a participant can instruct the biorepository to remove the individual's biospecimens and any associated data from the repository, but that the repository cannot retrieve biospecimens or clinical data already distributed to researchers.

Suggested checklist for biospecimen banking informed consent document: The attached template informed consent document prompts the drafter to explain the following items, all of which may be relevant to an individual's decision regarding whether to participate in a biospecimen bank:

- What is the purpose of the repository? What types of research will be conducted with the information and biospecimens collected?
- What type of information and biospecimens will be collected?
- How will the information and biospecimens be collected?
- How will the repository operate?
    - Where will the information and biospecimens be stored?
    - Who will have access to the information and biospecimens?
- Will there be any cost to the participants or their insurance companies for storage of the information and biospecimens in the repository?
- What confidentiality protections are in place?
    - Will the biospecimens be stored with any identifiers?
    - Will the biospecimens be coded? If so, who holds the key to the code?
- How long will the biospecimens be retained? After the research is done with the biospecimens, what will be done with them?
- Can participants withdraw their biospecimens and associated data from the biospecimen bank?
    - If so, how?
    - What happens to their information and biospecimens in the bank upon withdrawal?
    - Will the bank contact recipients to ask for return or destruction of any remaining specimens?
- What are the risks to participating?
    - What are the risks of the collection procedure, if any?
    - If identifiable information will be stored, what are the risks of release?
    - If genetic research is anticipated, does the consent include information about the consequences of DNA typing or other risks from release of genetic information?
- Will the participant be told about the research findings or have access to the research results?
- Will the participant be told about findings that may be clinically significant to them?
- If there is a commercial application developed, will the participant receive compensation?
- Does the consent include any prohibited "exculpatory language," such as: "I agree to give up all claim to personal benefit from commercial or other use of your tissue;" or "I voluntarily donate my tissue samples and relinquish all right, title and interest…"

NPRM Proposed Changes to Common Rule: The Office for Human Research Protections ("OHRP") issued a Notice of Proposed Rulemaking ("NPRM") on September 8, 2015, which proposes sweeping changes to the Common Rule, particularly regarding

biospecimen research. If the NPRM is finalized as proposed, the Common Rule would apply to more types of entities; would extend to de-identified biospecimens (in addition to identifiable biospecimens); would impose a 10-year time limit on the collection of biospecimens or information; and would impose new informed consent requirements, among other things.

As is particularly relevant here, if the NPRM is finalized as proposed, a biorepository consent would require slightly different elements:

- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that reasonably may be expected from the research;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- A general description of the types of research that may be conducted with information and biospecimens and the information that is expected to be generated from the research, the types of information or biospecimens that might be used in research, and the types of institutions that might conduct research with the biospecimens or information;
- A description of the scope of the informed consent, including:
    - a clear description of the types of biospecimens or information that were or will be collected and the period of time during which biospecimen or information collection will occur. This may include all biospecimens and information from the subject's medical record or other records existing at the institution at the time informed consent is sought; and
    - the period of time during which biospecimen or information collection will occur, which may not exceed 10 years from the date of consent. For research involving children as subjects, that time period cannot exceed 10 years after parental permission is obtained or until the child reaches the legal age for consent to the treatments or procedures involved in the research, whichever time period is shorter. The time limitations described do not apply to biospecimens or information that initially will be collected for research purposes;
- A description of the period of time during which an investigator can continue to conduct research using the subject's biospecimens and information (e.g., a certain number of years, or indefinitely);
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may withdraw consent, if feasible, for research use or distribution of the subject's information or biospecimens at any time without penalty or loss of benefits to which the subject is otherwise entitled, and information about whom to contact in order for the subject to withdraw consent. The statement must make clear that information or biospecimens that already have been distributed for research use may not be retrieved;
- If applicable, a statement notifying the subject or the representative that the subject or the representative will not be informed of the details of any specific research studies that might be conducted, including the purposes of the research, that will use the subject's information and biospecimens;

- If applicable, a statement notifying the subject or the representative of the expectation that the subject's information and biospecimens are likely to be used by multiple investigators and institutions and shared broadly for many types of research studies in the future, and this information and the biospecimens might be identifiable when shared;
- The names of the institution or set of institutions at which the subject's biospecimens or information were or will be collected, to the extent possible (in recognition that institutions might change names or cease to exist);
- If relevant, an option for an adult subject or the representative to consent, or refuse to consent, to the inclusion of the subject's data, with removal of the HIPAA "identifiers," in a database that is publicly and openly accessible to anyone. This option must be prominently noted, and must include a description of risks of public access to the data;
- If applicable, a statement that the subject's biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- If applicable, a statement regarding whether clinical relevant research results, including individual research results, will be disclosed to subject, and if so, under what conditions; and
- If applicable, an option for the subject or the representative to consent, or refuse to consent, to investigator's re-contacting the subject to seek additional information or biospecimens or to discuss participation in another research study.

Other Resources: Other template informed consent documents for biospecimen repositories include:

- NCI Group Banking Committee informed consent template: http://cgb.cancer.gov/resources/documents.html (follow link titled "Informed Consent Template (MS Word)"
- The Cancer Genome Atlas (informed consent document for prospective collection, addressing risks in genetic research): http://cancergenome.nih.gov/abouttcga/policies/informedconsent (follow link for "The Cancer Genome Atlas Suggested Language for Prospective Collections"
- The Electronic Medical Records and Genomics (eMERGE) Network Consent & Community Consultation Workgroup Informed Consent Task Force, Model Consent, http://www.genome.gov/Pages/PolicyEthics/InformedConsent/eMERGEModelLanguage2009-12-15.pdf

CONSENT TEMPLATE[17]

Consent to Participate in a Biospecimen Repository

Research is the key to developing new treatments and cures for disease. Medical information and biospecimens are very useful for research. You can support research by giving us permission to use your or your child's medical information and biospecimens for research. If you are consenting on behalf of your child, all of the references to "you" or "your" below refer to your child.

Human specimens include samples of blood, skin, bones, hair and other parts of the body. You have been given this consent form because *[insert holder of biospecimen bank]* wants to include your specimens in a biospecimen repository, or a "biospecimen bank," to use for future research. The *[insert name of biospecimen bank]* is located at *[insert location of repository]*.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a law designed to protect the confidentiality of your health information. This document seeks your permission to include your health information in the *[insert name of biospecimen bank]* to use for future research, and describes your rights about your health information.

How will your specimens be collected?
[Insert description of how specimens will be collected. For example, if they will only be excess tissue after treatment or diagnostic procedures, you could say: "You have had or are scheduled to have tests or procedures performed at [institution]. After these tests or procedures are completed, there may be leftover specimens that would be thrown away. Instead of having these leftover specimens thrown away, you can agree to let [institution] keep your specimens in the biospecimen bank for research."]

Who will keep your specimens?
[Insert discussion of who holds the research repository and how the repository is operated. Include a discussion of where the specimens will be stored, and who will have access to the specimens. Include a description of how long specimens will be kept. (Note that there is nothing in present federal law that requires a time limit for collection or retention; however, the NPRM has proposed changes to how long a consent can support future collection.)]

What type of information about me will be stored and what confidentiality protections are in place?
[*Insert explanation of what type of information is collected (such as the participant's medical records or other more limited parts of the record, such as laboratory results). This should also state whether identifiable or coded information will be maintained with the specimens or in a separate database, whether research results will be linked to specimens, and whether clinical data will be provided to the biospecimen bank in connection with the specimens (including whether that clinical data will be collected over time). It should state the name or specific identification of the persons or class of persons authorized to make the disclosure of PHI to the biospecimen repository (such as the participant's physicians and treating hospitals).]*

[17] This consent form would also meet HIPAA authorization requirements.

[Option 1: Insert for specimens linked to medical record information]
If you agree to participate, information about medical care you received in the past *[and that you will receive in the future]* will be collected from your medical record (such as test results, diagnoses, medications, immunizations and dates related to your care). This information may relate to treatment for sensitive conditions, such as HIV/AIDS, sexually transmitted and other communicable diseases, drug, alcohol or substance abuse, and mental health treatment, and may include genetic information. Demographic information about you (such as name, address, age, gender, race and family history) also will be collected.

We will collect this information from *[insert sources of information. Include "your health care providers" generically if you intend to collect medical records from other sources, such as the participant's primary care provider]*.

The information stored in the biobank will not include information that can directly identify you, such as your name, social security number, address, telephone number. Your biospecimens will be labeled with an identification number (a code).

Your name, address, phone number, and other identifying information will be kept separate from your biospecimens in a secure computer database at *[insert location of database]*. This secure computer database will include the identification number assigned to your biospecimens, which can be used to link you to your biospecimens if necessary. At *[insert name of biospecimen repository],* only the manager of the repository and other trusted personnel will have access to the information in this secure database. It is possible that agencies that regulate research, such as the Food and Drug Administration or the Office for Human Research Protections, will have access to this information, but they usually will not need to know your identity.

[Option 2: Insert for Unlinked Specimens.]
Once the specimen is collected, it will be separated or unlinked from your name or other ways to identify you. This will protect your identity and preserve anonymity. However, once you provide the specimen, you will not be able to withdraw your specimens from the bank because we will not know which specimen is yours.

[Insert if the participant will not be informed about research results:] Reports about research done with your specimens will not be given to you or your doctor. These reports will not be put in your medical record and it will not affect your care.

[Insert if the repository will be recontacting the participant's providers in the future to obtain more information about the participant:] In the future, people who do research may need to know more about your health. While the *[insert name of repository]* may give them information about your health, we will not give researchers your name, address, phone number, or any other information that will let the researchers know who you are.

What type of research will be done with your specimens?
[Insert discussion of what types of research will be conducted with the specimens collected. Example language: "Your medical information and biospecimens may be used for research relating to health, disease prevention, medical advancement, and other scientific purposes. This may include research on cancer, cardiovascular disease, stroke, diabetes and other metabolic disorders, neuroscience, urology, and other areas. Sometimes specimens are used for genetic

research (about diseases that are passed on in families).]

[Insert description of data sharing for NIH-funded GWAS studies: "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."[18]]

How will researchers get your specimens?
Researchers from universities, health organizations and private companies conduct research using biospecimens. They will contact the *[insert name or repository]* and request specimens for their research. A committee will review the way these studies will be done and decide if the studies have scientific or educational merits before we give your specimens to the researchers.

What are the benefits of participating?
The benefits of research using specimens for research include learning more about what causes diseases, how to prevent them, and how to treat them. The research that may be done with your specimens is not designed specifically to help you. It might help people who have diseases in the future.

What are the risks of participating?
[Insert explanation here if there are any risks associated with the physical collection of the specimens. For example, if there is a blood draw, consider inserting: "Having your blood drawn may cause mild bruising, swelling, and pain at the site at which the blood was taken. There is also a very small risk of infection at the site within the few days after the blood draw."]

[Insert if the specimens are linked to the participant: [Insert holder of biospecimen bank] has extensive precautions in place to prevent any unauthorized disclosure of personally identifiable information. However, if there is an accidental disclosure of information that can be used to identify you, it could affect your insurability, employment, family relationships or other legal rights. You should know that there are measures in place to prevent this from taking place. State and federal law, such as the Genetic Information Nondiscrimination Act (GINA), prohibit health insurance companies and larger employers from discriminating against people based on

[18] *See* The Electronic Medical Records and Genomics (eMERGE) Network Consent & Community Consultation Workgroup Informed Consent Task Force, Model Consent, http://www.genome.gov/Pages/PolicyEthics/InformedConsent/eMERGEModelLanguage2009-12-15.pdf.

their genetics. There may be unforeseeable risks that are not known at this time. However, you will be informed of any new risks as they become known.]

Once your health information is released to researchers, it may no longer be protected by the HIPAA law, although other confidentiality safeguards apply. If you have questions about your rights or how your health information will be protected, you can ask *[insert contact information]*.

How many other people have participated?
Over *[insert number]* other people have participated in the *[insert name of biospecimen repository]*.

Can you change your mind later?
Yes. If you decide now that your specimens can be kept for research, you can change your mind at any time. You may cancel your permission at any time by sending a written notice to *[insert contact information]*. If you cancel your permission, your *[insert type of serum/tissue]* and the information about you will be taken out of *[insert name of biospecimen repository]* and destroyed. However, your cancellation will not apply to information that has already been distributed for research purposes. *[Explain if the repository will contact recipient investigators when a participant withdraws participation and what happens.]* Unless you cancel this authorization, it will not expire. If you decide not to participate, it will not affect your care or any other benefits to which you are entitled.

Will you receive compensation?
No, you will not receive compensation for contributing your specimens to this research. *[Insert name or repository]* may share your specimens with researchers at universities, health care organizations and private companies. As part of such activity, the researchers may obtain patents or other legal licenses relating to possible diagnostic or treatment methods, which may lead to financial benefit for them. They do not have plans for you to share in this economic benefit. You do not waive any legal rights by signing this document.

Your Participation is Voluntary
The choice to let us keep your specimens for future research is up to you. You are not required to sign this form. If you decide not to sign this form or if you cancel it in the future, it will not affect your medical treatment, payment or eligibility for benefits, or enrollment in a health plan.

Where can I get more information?
If you have questions about your rights or how your health information will be protected, you can ask *[insert contact information]*.

Signature

I have been given a copy of all *[insert total of number of pages]* pages of this form. I have read this form or it has been read to me. I understand the information and I have had all my questions answered. I agree to participate in the Biospecimen Repository.

Signature of Participant _____ Date _____

Printed Name of Participant _____

Printed Name of Person Collecting the Consent _____

If Participant has a Personal Representative (someone who is authorized to make health care decisions on behalf of the Participant), the Personal Representative should sign:

Signature of the Personal Representative _____

Printed Name of Personal Representative _____

Date _____

Please describe why you have authority to make health care decisions on behalf of the Participant. (For example, are you the Participant's spouse or parent? Did the Participant name you as health care power of attorney?)

_____