Informed Consent for Protocols Involving Biospecimen Storage at a For-Profit Institution

The informed consent under which the specimen was collected must meet all the requirements in Appendix C of VHA Handbook 1200.05 "Requirements for the Protection of Human Subjects in Research." In addition, the informed consent must clearly address the following:

- **The types of specimens that will be stored and the name and location of the facility where they will be stored.**

  Example 1: Your blood and urine samples will be stored at Covance Central Laboratories in Indianapolis, IN, until the analysis is completed.

  Example 2: Your blood will be stored at Quintiles Lab in Marietta, GA.

- **The types of analyses/studies that the biospecimens will be used for.**

  Example 1: Your samples will be used to study proteins in the blood that could indicate the progress of heart disease.

  Example 2: Your blood sample will be analyzed for the amount of study drug and the substances that result from its breakdown.

- **The length of time the specimen will be stored.**

  Example 1: Your samples will be stored until the analyses are completed, but no longer than 1 year after the completion of the study. At that time, they will be destroyed.

- **That the specimen will be labeled with a code that does not contain any personal identifiers (i.e., protected health information as defined by HIPAA).**

  Example 1: The sample and your clinical data will be assigned a code that does not contain your name, initials, SSN, date of birth, or other unique identifiers.

  Example 2: All identifiable information about you will be removed from the research specimen. Your sample and data will be identified by a code.

- **When and under what conditions research results will be conveyed to the subject, the subject's family, or the subject's physician.**

  Note: Laboratories that test human specimens cannot report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment

of, or the assessment of the health of individual patients unless the laboratory is Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified.

Example 1: These tests are being done for research purposes only; you and your doctor will not be informed of the results.

Example 2: Reports about research done with your samples will not be given to you or your doctor because they will not have any direct clinical benefit to you at this time.

Example 3: You and your doctor will be given the results of your blood tests for kidney function; however, you will not be given reports about tests performed strictly for research.

- **The steps necessary for the subject to withdraw from the study. The consent must indicate what will occur to the data collected to that point, and what will happen to the samples already collected.**

  Example 1: You may withdraw your consent at any time. Please notify Dr. Smith at <phone number> to withdraw your consent. Your blood samples and all links to your clinical data will be destroyed at the end of the study. Any research data already collected on you cannot be destroyed, but no further data will be collected.

  Example 2: You may ask the researchers to stop using your health information at any time. Contact Dr. Smith at <phone number>. The research team will continue to use any information that they have already collected to ensure the integrity of the research. However, no new information will be collected from you. In addition, your samples will be destroyed.

- **Disclose if the subject will receive money or other benefits if a drug or product is marketed.**

  Example 1: Your specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value. You will not receive any money or other benefits derived from any commercial or other products that may be developed from the use of the specimens.

  Example 2: The use of your sample may result in inventions or discoveries that could become the basis for new procedures of diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed. Commercially available products may be developed from these samples. There are no plans to share any of these profits with you.

- **Disclose any intent to perform genetic tests.**

  Example 1: Genetic tests will be confined to testing for genes relating to hepatitis C.

  Example 2: Genetic material (DNA) will be isolated from the blood or tissue sample that you donate. It will only be used to test for genes relating to prostate cancer.

- **If genetic analysis will be performed, disclose any potential risks to the subject or the subject's family. Potential risks may include breach of confidentiality, which may lead to discrimination in the areas of employment, insurability, social stigmatization, or psychological stress caused by disclosure of adverse information to the subject or the subject's family.**

  Example 1: It is theoretically possible that genetic information about you could lead to denial of insurance or employment. Therefore, information about you will not be given to other family members (unless you give permission, or unless you need a representative at a later date), insurance companies, or employers.

  Example 2: The study results might be stressful to you if we were to find that you carry a gene for a neurological disease.

  Example 3: We will make every effort to protect your confidentiality and make sure that your identity does not become known. All written information will be stored in a locked file cabinet, and electronic data will be encrypted. A limited number of staff members will have access to the data. However, there is a slight risk of a breach of security.

Informed Consent for Protocols Involving Tissue Banking at a Non-profit Organization

The informed consent under which the specimen was collected must meet all the requirements in Appendix C of VHA Handbook 1200.05 "Requirements for the Protection of Human Subjects in Research." In addition, the informed consent must clearly address the following:

- **The types of specimens that will be stored and the name and location of the biorepository/tissue bank where they will be stored.**

  Example 1: Your blood and DNA samples will be stored at the National Cell Repository for Alzheimer's Disease (NCRAD) in Indianapolis, IN.

  Example 2: Your DNA will be stored at the Rutgers University Cell and DNA Repository in Piscataway, New Jersey.

- **The types of future research that the sample will be used for.**

  Example 1: Your DNA and serum will be stored for genetic testing. Genetic testing will be restricted to testing for genes related to dementia.

  Example 2: Your blood samples will be used for studies of any major disease or health condition, including genetic studies.

  Example 3: Your samples will be used for research on Alzheimer's disease and related diseases.

  Example 4: see Example 3 in the next section.

- **If the specimen will be shared with other researchers for approved research protocols.**

  Example 1: The National Institute on Aging (NIA), a component on the National Institutes of Health (NIH), will make your DNA and clinical data available to other qualified scientists.

  Example 2: Your blood will be shared with other qualified researchers at the Bronx VAMC.

  Example 3: If you give permission, samples may be shared with other research laboratories studying the genetics of type 2 diabetes and the development of heart and blood vessel diseases, other major disease, health conditions, or risk factors.

__I agree to allow my genetic sample to be studied for genes related to any major disease or health condition or risk factor.

__I agree to allow my genetic sample to be studied only for genes related to diabetes, blood pressure, blood cholesterol abnormalities, heart disease, or other risk factors for heart disease or for diabetes.

__I agree to allow my genetic samples to be used only for this study.

- **The length of time the specimen will be stored.**

  Example 1: Your samples will be stored for 15 years and then destroyed.

  Example 2: Your samples will be stored until none is left.

  Example 3: Your samples will be stored indefinitely.

- **That the specimen will be labeled with a code that doesn't contain any personal identifiers (i.e., protected health information as defined by HIPAA) and if the subject's clinical data will be linked to the specimen.**

  Example 1: The sample and your clinical data will be assigned a code that does not contain your name, initials, SSN, date of birth, or other unique identifiers.

  Example 2: All identifiable information about you will be removed from the research specimen. Your sample and data will be identified by a code.

- **When and under what conditions research results will be conveyed to the subject, the subject's family, or the subject's physician.**

  Note: Laboratories that test human specimens cannot report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients unless the laboratory is Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified.

  Example 1: These tests are being done for research purposes only; you and your doctor will not be informed of the results.

  Example 2: Reports about research done with your samples will not be given to your or your doctor because they will not have any direct clinical benefit to you at this time.

  Example 3: Because these results have no clear meaning for you at this time, we will not report the results of the XYZ testing to you. XYZ testing is not a proven marker for Alzheimer's disease.

- **The steps necessary for the subject to withdraw from the study and any future studies in which the specimens may be used. The consent must indicate what will occur to the data collected to that point and that the specimen and the code that links the subject's clinical data to the specimen will be destroyed.**

  Example 1: You may withdraw your consent at any time. Please notify Dr. Smith at <phone number> to withdraw your consent. Your DNA, plasma, and all links to your clinical data and any data obtained from this research study will be destroyed.

  Example 2: You may withdraw your consent at any time. Please notify Dr. Smith at <phone number> to withdraw your consent. Your DNA, plasma, and all links to your clinical data stored in the repository will be destroyed. However, any de-identified samples that have been shared with other researchers cannot be destroyed.

  Example 3: You may ask the researchers to stop using your health information at any time. Contact Dr. Smith at <phone number>. The research team will continue to use any information that they have already collected to ensure the integrity of the research. However, no new information will be collected from you.

- **Disclose any potential commercial benefits and if the subject will receive money or other benefits.**

  Example 1: Your specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value. You will not receive any money or other benefits derived from any commercial or other products that may be developed from the use of the specimens.

  Example 2: The use of your sample may result in inventions or discoveries that could become the basis for new procedures of diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed. Commercially available products may be developed from these samples. There are no plans to share any of these profits with you.

- **Disclose any intent to perform genetic tests.**

  Example 1: Genetic tests will be confined to testing for genes relating to liver diseases, including hepatitis and cancer.

  Example 2: Genetic material (DNA) will be isolated from the blood or tissue sample that you donate. It will be used to test for genes relating to prostate cancer.

- **Disclose any potential risks to the subject or the subject's family. Potential risks may include breach of confidentiality, which may lead to discrimination in the areas of employment, insurability, social stigmatization, or psychological stress caused by disclosure of adverse information to the subject or the subject's family.**

  Example 1: It is theoretically possible that genetic information about you could lead to denial of insurance or employment. Therefore, information about you will not be given to other family members (unless you give permission, or unless you need a representative at a later date), insurance companies, or employers.

  Example 2: The study results might be stressful to you if we were to find that you carry a gene for a neurological disease.

  Example 3: We will make every effort to protect your confidentiality and make sure that you identity does not become known. All written information will be stored in a locked file cabinet, and electronic data will be encrypted. A limited number of staff members will have access to the data. However, there is a slight risk of a breach of security.