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**Constructing a Consent Document for a Research [Tissue or Data] Bank which will Collect, Store or Use [Human Biological Materials and/or Data] for Future Research**

**PURPOSE**: This guidance document may be used as a resource for investigators who wish develop consent documents for research [tissue or data] bank activities.

**ROADMAP:**  The reader will find two areas of guidance: **Section I** offers a brief review of the documents that must be submitted to the IRB for review prior to engaging in banking activities (page 1). **Section II** offers a consent template, complete with sample text you may use to guide the development of a consent form for your project (page 2-19).

**SECTION I. PROCEDURAL GUIDANCE FOR IRB SUBMISSION AND REVIEW:**

1. Develop a **Standard Operating Procedures Manual** for the conduct of the Research [Tissue or Data] Bank. Guidance on what topics should be addressed in the manual may be found at <https://orra.rutgers.edu/formsandtemplatesirb> .
2. Compose a **consent document** that you will use to secure subjects’ permission to collect, store, and/or distribute [samples and/or information], if applicable. A suggested consent template may be found in Section II of this document.
3. Fill-out an **IRB Initial Application (An Application specific to banking activities is forthcoming. But for now, fill out the standard IRB Initial Application.)**  [https://eirb.rutgers.edu](https://eirb.rutgers.edu/)
4. Submit the following documents via e-IRB to request IRB review of your project:
* Standard Operating Procedures for a Research [Tissue or Data] Bank;
* Consent Document for the Participation in a Research [Tissue or Data] Bank;
* A completed IRB Initial Application; and
* A copy of the complete grant/contract, if funded.

Research [Tissue or Data] Bank applications are initially reviewed by the Executive IRB. Subsequent reviews are referred to regular IRB Committees on a case-by-case basis. Contact the IRB office if you require clarification of the IRB review process.

**SECTION II. CONSTRUCTING A CONSENT DOCUMENT**:

Revise the following consent template by adding, deleting or modifying the sample text to accurately reflect your proposed banking activities. **Instruction**: Boxes (containing guidance and explanations of purpose) appear below each required section. **[Brackets]** embedded within the sample text likewise provide instruction to you but not the potential subjects. Please delete **Instruction**: Boxes and replace **[Brackets]** and sample text with appropriate language that best reflects your banking activities before submitting the consent form for IRB review and approval. When finished the form should be about 7 or 8 pages long.

**A CONSENT FORM FOR**

**THE COLLECTION, STORAGE AND USE OF [[BLOOD, TISSUE OR OTHER BIOLOGICAL MATERIALS AND HEALTH INFORMATION] OR [HEALTH INFORMATION]**

**FOR FUTURE RESEARCH STUDIES**

**PROJECT TITLE: [Insert Project Title]**

**PROTOCOL NUMBER:** **[Insert Protocol Number]**

**PRINCIPAL INVESTIGATOR: [List Principal Investigator name, address, telephone#**

 **and e-mail address as appropriate]**

**RESEARCH [TISSUE or DATA] BANK: [Insert Bank name, primary contact name, address,**

 **telephone#, days of week/hours when best to call,**

**web address if available]**

**SPONSOR OF THE BANK: [Insert Sponsor name and address, if applicable, otherwise**

 **delete]**

**IRB OFFICE:** IRB Director **[list the appropriate campus]**

 65 Bergen Street 335 George Street

 SSB Suite 507 Liberty Plaza Suite 3100

 Newark, NJ 07101 New Brunswick, NJ 08901

 (973) 972-1149 (732) 235-9806

**SUMMARY**

You are being asked to provide **[specify type of sample OR information about \_\_\_\_\_\_\_]** to be stored in a research **[tissue OR data]** bank for future research on **[specify topic or indicate “medical topics not yet determined”. If genetic research is anticipated, specify that here as well. Offer a definition of what you mean by genetic research.]**. The purpose of this consent form is to help you decide if you want to take part in this research.

**What is the Consent Process?**

The consent form is part of an informed consent process for the collection of **[specify type of sample OR information about \_\_\_\_\_\_\_]** for research. The form tells you important information about the research [**specify genetic research, if anticipated]**, the research procedures and information about you to be collected, and a research **[specify tissue OR data]** bank, the place where your **[specify sample AND/OR information]** will be stored. A member of the study staff will tell you about the research, review this form with you, and answer your questions about the research.

The form is arranged as a series of questions we think are important to be answered for you before you make your decision. Please feel free to ask other questions. Please ask the study staff to explain any words or information provided in this document that you do not understand. You should feel free to ask questions and should expect answers that you understand. You may take home a copy of this consent form to think about or discuss with family or friends before making your decision.

After all of your questions have been answered and you want to take part in the research **[tissue OR data]** bank by providing a **[sample and/or information]**, you will be asked to sign this consent form to indicate your permission to take part in the research and allow investigators to collect and use your health information (some of the information may be personal information traditionally used to identify you, such as your name, address, telephone number or medical record number). We will give you a copy of the consent form to keep. If you do not want to take part in the study or allow use of your personal or private health information, say no and do not sign the consent form. Your decision to take part or not to take part does not affect your relationship with the study staff, your medical care, or any benefits to which you are otherwise entitled.

* If you have any additional questions about the research, please contact the principal investigator **[Insert name and telephone number]**.
* If you have any questions about your rights as a subject in research, please contact the Rutgers IRB Office **[Insert telephone number of the appropriate campus IRB]**. You may also find information about research at Rutgers at the following website address <http://www.rutgers.edu/research/research-rutgers>.

**Why am I being asked to take part in the Research [Tissue OR Data] Bank?**

**Instruction:** Please provide an explanation in lay language (at a 6th - 8th grade reading level) based on the protocol’s inclusion/exclusion criteria and state the approximate number of subjects you anticipate will participate in the Research [Tissue or Data] Bank]. Sample text to get you started is offered below.

You are being asked to provide **[specify, i.e., blood, tissue, urine, information, etc.]** because **[explain**…]

We expect **[specify number of subjects]** people will take part in this Research [Tissue or Data] Bank.

**What is the relationship between the Investigator [and the Sponsor] and the Research [Tissue OR Data] Bank?**

**Instruction:** Identify the name of the Sponsor and/or Research Tissue or Data Bank here and disclose the relationship between them, as applicable. Sample texts of different types of relationships are offered below. Please be specific.

**Sample Text #1 Investigator is Owner/Operator:**

The investigator is the owner and operator of the research **[tissue OR data]** bank.

**Sample Text #2 Sponsor Pays Investigator and Operating Expenses:**

**[Insert name of Sponsor]** is the sponsor of this research and the research **[tissue OR data]** bank. The investigators are being paid for their professional services to create and maintain the research **[tissue OR data]** bank according to a budget that will cover the costs of its day-to-day activities. Expenses that are usually paid for by the sponsor are such things as testing and the costs of collecting and storing data associated with your **[samples AND/OR information]**.

**Sample Text#3 Sponsor/Investigator/Bank Affiliation Agreement:**

**[Insert name of Sponsor and/or Research Tissue or Data Bank]** has/have an affiliation with the investigator and Rutgers. **[Explain the affiliation.]**

**Sample Text#4 Investor Relationships/Patents/Financial Gain:**

 **[Insert name of Investigator and/or Rutgers] are** investors with **[Insert name of Company/Sponsor]**. The investigators and Rutgers are joint owners of a patent for this **[explain, i.e., microarray, novel antibody, etc.]** and are **[co-owners of the Research Tissue or Data Bank]**. They may gain financially from any patents or discoveries that may result from research done using your **[samples AND/OR information]** you provided to the research **[tissue OR data]** bank.

**What is the purpose of this research [tissue or data] bank?**

**Instruction:** Describe the nature and purpose of the research tissue OR data bank as outlined in the protocol. Please be sure to use language that a lay audience (6th - 8th grade reading level) can understand. Sample language for a research tissue bank appears below. Modify language for a research data bank as appropriate.

In general, research tissue banks store collected tissue samples, such as blood, tissue and other bodily fluids or materials, and health information from the people who provide those samples. The purpose of a research tissue bank is to store samples and health information until researchers need them for research studies. **[If genetic research is anticipated, consider adding the following sentence here: Among other things, samples and information may be used to study how genes (what traits we inherit from our ancestors), proteins, lifestyle, and environment may lead to disease, and to study how people respond to medical treatment.]**

 The long-term goals of this research tissue bank are to better understand disease and to develop better means to prevent, diagnose and treat **[specify what disease or insert “disease” if specific disease has not yet been defined]**. There is no set limit to the number of individuals that provide samples and information to this tissue bank. The more samples and health information available in the tissue bank, the more useful the tissue bank will be for medical research.

**For what type of research will my [samples and] information be used?**

**Instruction:** There are several options you should consider: (1) You may wish to restrict use of the samples or data to research related to a specific disease/condition/topic under study (see Sample Text #1); or (2) Less restrictive, you may wish to use samples or data for research related to a specific condition AND unrelated research (see Sample Text #2); or (3) Least restrictive, you may wish to use samples or data for any research of medical interest (Sample Text #3); or (4) You may offer the participant a choice to restrict research on or access to their samples or data (see Sample Text #4). **Note: If genetic research is anticipated, Rutgers, guided by current bioethics literature on the subject, strongly encourages investigators to offer participants the opportunity to choose (see Sample Text #4) If stem cell research is anticipated, contact the IRB office for guidance.** Please be sure that whichever option you choose, it is consistent with the protocol and the text you use in the consent section entitled “What is the purpose of this research tissue or data bank?” and that you have procedures in place to ensure you use tissues or data only for purposes authorized by the participant.

Sample language appears below. Modify language as appropriate.

**Sample Text #1 Research Related Only to Specific Disease:**

Your **[samples and]** information will be used mainly to **[state the purpose of this collection and type of research which will be performed; specify that the research includes genetic research if applicable]**. The long-term goals of the research are to better understand, prevent, diagnose or treat **[specify disease]**. However, it is not possible to list every research project. Also, we cannot predict all of the research questions that will be important in the coming years. As we learn more, there are new research questions and new types of research related to **[specify disease]** that may be done.

**Sample Text #2 Research Related to Specific Condition and Unrelated Research:**

Your **[samples and]** information will be used mainly to **[state the purpose of this collection and type of research which will be performed; specify that the research includes genetic research if applicable]**. The long-term goals of the research are to better understand, prevent, diagnose or treat **[disease]**. However, it is not possible to list every potential research project. Also, we cannot predict all of the research questions or studies that may be important in the coming years. As we learn more, there are new research questions and new types of research related to **[specify disease]** that may be done. Your **[samples and]** information may also be used for research on other conditions unrelated to the current project, for example, as comparisons to other diseases or medical conditions.

**Sample Text #3 Any Research of Medical Interest:**

Your **[samples and]** information will be used to learn how to better understand, prevent, diagnose or treat disease [**specify that the research includes genetic research if applicable]**. We cannot predict all of the research questions that will be important in the future. As we learn more, there are new research questions investigators may ask and different types of research they may perform of interest to medical science that have not yet been identified.

**Sample Text#4 Subject Chooses How Samples/Information Used:**

Your **[samples and]** information will be used mainly to **[state the purpose of this collection and type of research which will be performed, including genetic research if applicable]**. The long-term goals of the research are to better understand, prevent, diagnose or treat **[specify disease]**. However, it is not possible to list every research project. Also, we cannot predict all of the research questions that may be important in the future. As we learn more, there are new research questions and new types of research related to **[specify disease]** that may be done. Your samples and information may also be helpful for future research on other diseases or conditions. Please indicate below how you wish your samplesand information to be used for research (choose one):

 \_\_\_\_ (initial) I permit my **[samples and]** information to be stored and used for research of the

 disease or condition being studied **[specify disease]**

**OR**

 \_\_\_\_ (initial) I permit my **[samples and]** information to be stored and used for research to

 to learn about, prevent, or treat the disease or condition being studied **[**specify **disease]**

 **AND** any other diseases or medical conditions.

**How will my [samples AND/OR information] be collected?**

**Instruction:** Explain how biological materials and/or information will be collected. Identify any procedures which are experimental and/or are in excess of standard of care. If existing clinical/research samples will be collected, please state that here as well. Sample text appears below. **Delete** this first section if you are only collecting data and skip to the next instruction under the same heading.

* We will collect a blood sample from you by drawing about **[specify amount in lay terms, i.e., 2 teaspoons]** of blood from a vein in your arm (the sample collected is in addition to the **[specify amount]** that was collected for standard medical care you are currently receiving);

**[AND/OR]**

* We will collect a urine sample from you by **[explain]**;

**[AND/OR]**

* We will collect a **[specify]** sample from you by **[explain]**;

**[AND/OR]**

* If a **[specify]** sample was collected from you during previous **[specify surgery or medical procedure]**, we seek permission to receive some of this sample for research and storage in the tissue bank only after it has been used for the original medical purpose of collection**.**

**Instruction:** Provide (1) a summary of the demographic, medical or other personal information you will ask participants to provide or you will collect from them, (2) how you will collect it, (3) from where you will collect it, and (4) whether data collection will be one-time or on-going. Sample text appears below. **PLEASE NOTE**: Depending on the location from which information is collected, additional approvals from that location may be required. For more information, go to <https://orra.rutgers.edu/formsandtemplatesirb> and find the appropriate “Performance Site Form”, if applicable.

We also will collect information about you **[specify how, i.e., “by asking you to complete a questionnaire,” “by asking you a few questions about your health history,” and/or “by reviewing information in your medical record at (specify location).”]** Some information we will collect about you is personal information that may be traditionally used to identify you, such as **[specify what personal identifiers will be collected, i.e., “your name, address, telephone number, or medical record number”].** Other information we may collect includes **[specify what information, i.e., “your age, sex, race, ethnicity, family medical history, diagnosis, disease history, prior medical treatments, or responses to medical treatments.”]** Additionally, some of the information **[specify]** will be collected by our investigators at the time you begin participating in the research. Other information **[specify which information, such as “diagnoses and medical treatments”]** will be collected **[specify when, such as “periodically,” or “annually for as long as we have your samples.”]**

Investigators, whose studies have been approved by the Rutgers Institutional Review Board, or “IRB”, may be allowed to review your medical record to collect more information about you. The IRB is a committee that independently reviews and approves research studies that involve people at Rutgers and other facilities that have asked them to review their research. The IRB follows state and federallaws and codes of ethics to help protect the rights and welfare of people taking part in research.

**How will my [samples AND/OR information] be coded and stored?**

**Instruction:**  Because medical research can reveal clinical and personal information about individuals, investigators must ensure that those who participate in research by providing their samples and health information are adequately protected from unwarranted harms resulting from the inadvertent release of such information. Provide an easy to understand description of how samples and/or health information will be coded and stored. Highlight the ways in which participants’ privacy will be protected and samples and associated data will remain confidential. Sample text appears below.

To protect your privacy, your **[specify: samples, medical information and/or personal identifiers]** will be labeled with a code. Only **[specify investigator’s name(s)]** at **[specify institution]** will have the code that links to personal information traditionally used to identify you, such as your name, address, telephone number, or medical record number. **[Specify name]** will keep the code in a safeguarded information file, or database. Only very few, authorized people, who have agreed to protect your identity and information, will have access to this database. All other investigators and staff, including those who will be working with your **[samples and]** information, will not have access to the code or any information traditionally used to identify you.

**Which researchers can use my [samples and] information and what information about me can they have?**

**Instruction:** Outline your plans for sharing samples or data. Specify who will have access to samples OR data OR both: only you?; your research group?; others at Rutgers?; outside academic and/or commercial collaborators? Consider both current research needs and possible future scenarios, such as if/when co-investigators dissolve their relationship or leave the employ of Rutgers. Sample text of three possible scenarios for sharing samples or data with others: (1) sample and/or data sharing is limited to your own research group; (2) samples and/or data may be used by other researchers at Rutgers; and (3)samples and/or data may be shared with investigators outside of Rutgers. Please make sure the language about what type of research (specific disease or condition vs. future unspecified research) is consistent with the protocol and what you say in the section entitled, “For what type of research will my samples be used/” and must be reflected in your policies and procedures. **PLEASE NOTE:** Regardless of sample/data-sharing arrangements, research tissue or data banks **MUST** limit distribution of identifiable information and only allow researchers’ use of coded samples with no access codes that link identifying information. (**PLEASE NOTE:** Data transfer agreements must be executed before data may be shared. Contact the IRB Office to review the elements of such agreements.)

**Sample Text #1 Sharing Limited to Your Own Research Group:**

Your **[samples and]** information stored in this research **[tissue OR data]** bank and information files, or database, are limited for use by our own laboratory’s research on **[specify disease]**. Your **[samples and]** information will not be made available to other investigators now or in the future.

**Sample Text #2 Sharing Limited to Us and Other Researchers at Rutgers:**

 Your coded **[samples and]** information will be used by our own investigatorsand other IRB-approved investigators at Rutgers researching **[specify disease]**. The research **[tissue OR data]** bank will provide investigators coded **[samples and limited]** information that does not identify you. We will not provide information that is traditionally used to identify you such as your name, address, telephone number or medical record number now or in the future. While your coded **[samples and]** information may be shared with other investigators, they will not be sold to them for profit.

**Sample Text #3 Sharing Includes Rutgers & Non-Rutgers Researchers:**

Your coded **[samples and]** information will be used by our own investigators, other IRB-approved investigators at Rutgers researching **[specify disease]**, and other investigators at non-Rutgers institutions researching **[specify disease]**. Your coded **[samples and]** information may be shared with investigators at academic, governmental or for-profit companies that are working with Rutgers investigators on **[specify condition]** research**.** The research **[tissue OR data]** bank will provide investigators coded **[samples and]** information that does not identify you. We will not provide information that is traditionally used to identify you such as your name, address, telephone number or medical record number now or in the future. While your coded **[samples and]** information may be shared with other investigators and institutions, they will not be sold to them for profit.

**What agencies and officials may use or share the protected health information collected about me?**

 The following Rutgers parties are authorized to use and share your protected health information in connection with this research study:

* The Rutgers Institutional Review Board ( a committee that independently reviews and approves Rutgers research studies)
* Other Rutgers officials responsible to oversee research

**Instruction:** Add to the list all classes of persons or organizations affiliated with Rutgers who might need to use and/or disclose the participant’s protected health information in connection with this research.

The parties listed in the preceding paragraph may share your protected health information with the following persons and organizations for their use in overseeing this research:

* The Office for Human Research Protections in the U.S. Department of Health and Human Services

**Instruction:** Add to the list all classes of persons or organizations not affiliated with Rutgers (for example, a sponsor, data safety monitoring board, collaborators at other institutions, outside data analysts, the National Institutes of Health, the Food and Drug Administration, etc.) to whom the participant’s information might be disclosed.

Your information may be shared with others by the organizations described above. After it is shared, Rutgers is not in a position to control whom they then share the information with if they are not required by law to protect the privacy of the information.

**How long will my [samples and] information be kept?**

**Instruction:** Outline anticipated time of storage of samples and/or information, as well as codes. Sample text for a research tissue bank appears below. Modify as appropriate for a research data bank.

There is no scheduled date on which your samples and information in the research tissue bank will be destroyed. In some cases, samples may be stored until they are used by investigators. In other cases, samples may be used to create a “cell line” (other cells may be grown from it), which will be stored and used for research indefinitely. The code linking your samples to your information may be kept indefinitely so that your samples and information may be used for research in the future. The research tissue bank may also destroy your sample and delete your health information at any time without notice to you.

**Will you contact me in the future with additional requests?**

**Instruction:** If you do not anticipate a need to contact participants in the future, delete this section. If it is applicable, you must have policies and procedures to ensure you only contact participants consistent with their wishes.

In the future we may want to request additional samples or follow-up with you about your health or medical care. Should this be needed we would like permission to contact you. If you give us permission, a person from **[specify]** will contact you either by telephone or letter to ask whether you would be interested in participating in this additional research. Please indicate (initial) your wishes (choose one):

 \_\_\_\_ (Initial) I permit Rutgers to contact me in the future for additional samples or information.

 (You may be asked to sign a new consent form at that time.)

 **OR**

 \_\_\_\_ (Initial) I do not permit Rutgers to contact me in the future for additional samples or

 information.

**Can I stop allowing [my samples and] information to be stored and used for research?**

**Instruction:** Sample texts appear below: Sample Text #1may be used if it possible for participants to withdraw their samples and/or information from the research tissue/data bank. Sample Text #2 may be used if it is not possible for participants to withdraw their samples because the samples have been stripped of all identifiers and codes that link to the identifiers prior to storage.

**[Sample Text #1] If Participants Can Withdraw Samples/Information:**

 **It may be possible to withdraw some samples and information.**

* If you would like to withdraw from participating in this project at some point in the future you can contact **[insert name]** at **[specify institution]** and he or she will destroy any **[specify: remaining tissue samples or data]** of yours that are currently being stored in the Research **[Tissue or Data]** Bank. **However**, it will not be possible to destroy the **[samples, information and]** data generated **[from your samples]** that may have already been distributed to investigators or placed in research files or databases prior to the time of your request to withdraw.
* If you wish to withdraw the personal information and private health information that you provided, please contact [**insert name**] in writing at [**insert address**]. At that time, it may also be possible for him or her to destroy the code linking you to the information you provided.

**[Sample Text #2] Samples and/or Information Cannot be Withdrawn:**

No. The **[specify samples OR information]**, once provided to the research **[tissue OR data]** bank, are not linked to codes that can identify your **[sample AND/OR information]** from other participants’ **[samples AND/OR information]**. Therefore it is not possible to withdraw your **[samples AND/OR information]** once they are given to the research **[tissue OR data]** bank.

**When will my authorization (permission) for the use of the health information traditionally used to identify me, (such as my name, address, telephone and medical record number) end?**

**Instruction:** If an end-date for the use of protected health information is known, list it here. See Sample Text#1. If you are uncertain as to when the authorization will expire, see Sample Text#2.

**Sample Text #1 Authorization End-Date Known:**

Your authorization for the use and/or disclosure of your health information traditionally used to identify you **[specify the personal identifiers collected]** will expire on **[specify date].**

**Sample Text#2 No Authorization End-Date Known:**

There is no set date at which your authorization will expire. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

**What are the risks of harm to me?**

**Instruction:** Describe in lay language (6th - 8th grade reading level) what the physical risks of harm and discomfort associated with each type of procedure/intervention to obtain specimens. If the incidence of these risks of harm or discomfort is known, it should be stated (e.g., rare, occasional or common). Skip this section if this is a research data bank and proceed to the next instruction under this heading. **Please Note:** If specimen volume is greater than “accepted, standard practice”, it may create a greater risk of harm and should be so stated. Sample text appears below.

Physical Risks of Harm

Study staff will explain the risks of harm from procedures used to collect blood, tissue, bodily fluids or other biological samples for research. They are listed below. In some cases, study staff may ask you to sign a separate clinical consent form that explains the risks of harm from the procedure. Allowing your samples to be stored in the research tissue bank will not change the risks of harm from the medical procedure itself.

* If a blood sample is taken from you, there are few risks of harm. Possible effects from drawing a blood sample include mild pain, bruising and infection at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually last only a few minutes. Infection is rare.
* If a urine sample is collected from you, there are no known physical risks of harm.
* If a **[specify procedure]** sample is collected from you, the possible effects are **[explain]**.
* If a sample was collected during a previous **[specify surgery or medical procedure]**, there is no new risk of physical harm.

**Instruction:** Describe in plain language the psychological or social risks of harm associated with loss of privacy. Sample text appears below. When human genetic research is anticipated, additional psychological or social risks apply. Sample text specific to genetic research appears in the second “bullet” offered below.

Psychological or Social Risks Associated with Loss of Privacy

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all the safety measures that we will use, we cannot guarantee that your identity will never become known.

* While the databases developed for this project will be coded and will not contain information that is traditionally used to identify you, such as your name, address, telephone number, or medical record number, people may develop ways in the future that would allow someone to link your medical information in our protected databases back to you. It is also possible that there could be violations to the security of the computer systems used to store the codes linking your medical information to you.
* Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives (for example, to establish blood relationships between parents and their children).
* There also may be other privacy risks that we have not foreseen.

**Instruction:** When human genetic research is anticipated, economic risks of harm must also be outlined. Sample language appears in the first bullet below. Language in the second bullet is required by federal law: “Genetic Information Non-Discrimination Act”. Further information about the federal law may be found at: <http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html>.

Economic Risks of Harm

* Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic distress.

There are state and federal laws that protect against genetic discrimination:

* There is a 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. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) 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. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**Instruction: PLEASE NOTE:** Certificates of Confidentiality constitute an important tool to protect the privacy of research study participants. Certificates are issued by the National Institutes of Health to protect identifiable research information from forced disclosure. They may be granted for studies collecting information or developing new health information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants. For further information on how to apply to the NIH for a certificate, go to <http://grants.nih.gov/grants/policy/coc/>.

**What will happen if I am injured taking part in the Research [Tissue OR Data] Bank?**

**Instruction:** There are three different texts offered below. Choose only those categories applicable to your research project (depending on your research, you may need to use more than one category). Include the last paragraph following Category 3 regardless of which Category you choose. This section and its language are mandatory. Choose only those categories appropriate to your research. Fill in the blanks where indicated. Any exception to these statements must be approved by the Dean, the administrator of the patient care unit, the Executive Vice President for Academic and Clinical Affairs and the Director of Risk and Claims Management. **PLEASE NOTE:** Minimal risk studies do not require this section. As a general rule, Research Tissue/Data Banks (that do not anticipate future genetic research) are considered minimal risk activities. If your project is deemed minimal risk, please delete this section.

**Category 1: For research on healthy volunteers:**

Subjects in this study will be exposed to certain risks of personal injury, which include **[provide a complete description if not provided elsewhere in the consent form, or refer the reader to the appropriate section of the form]**. In addition, it is possible that during the course of this study, new adverse effects of **[fill in the name of the drug, device, procedure, etc.]** that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject’s health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

**Category 2: For research on patients with a disease or medical condition:**

Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include: **[provide a complete description if not provided elsewhere in the consent form, or refer reader to appropriate section of the form].** In addition, it is possible that during the course of this study, new adverse effects of **[fill in the name of the drug, device, procedure, etc.]** that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject’s health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

**Category 3: All consent forms provided to patients seeking treatment under a single-patient-treatment, emergency use or compassionate use (also known as early or expanded access) protocol involving more than minimal risk:**

Patients seeking treatment under **[fill in the name of the single patient treatment, emergency use or compassionate use protocol]** will be exposed to certain risks of personal injury in addition to those associated with standard forms of therapy, which include **[provide a complete description if not provided elsewhere in the consent form, or refer the reader to the appropriate section of the consent form]**. In addition, it is possible that during the course of this treatment, new adverse effects of **[fill in the name of the drug, device, procedure, etc.]** that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for patients who sustain personal injuries or illnesses as a direct consequence of the treatment. The patient’s health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The principal investigator’s name and telephone number are listed on the first page of this consent form. You are not giving up any of your legal rights to obtain compensation for injury by signing this consent form or by taking part in this research.

**What are the benefits to me?**

**Instruction:** In lay language, please itemize the benefits to people that participate in this research. Compensation for their time to participate is not considered a benefit and should not be listed here. Sample text appears below.

You will not benefit personally from providing a **[sample and]** information for this project because research usually takes a long time to produce meaningful results. However, your participation may help investigators understand, prevent, or treat the diseases and conditions studied in the future.

**What are my alternatives if I do not want to take part in the Research [Tissue OR Data] Bank?**

**Instruction:** Sample text appears below.

Your alternative is not to provide **[samples and]** information to this research **[tissue OR data]** bank.

**Will I get results of the research done using my [samples and] information?**

**Instruction:** If results will not be shared with subjects, consider the sample text which appears below.

No. The research we are doing is only a stepping stone in understanding **[specify disease or condition]**. It may take a long time for this project and related research to produce health-related information that we will know how to interpret accurately. Therefore, tests done for this research using your **[samples and]** information will not be useful in directing your medical care. Information from this research will not be returned to you, your family members, your doctor, or outside parties.

**Instruction:** If you have a newsletter or other way of *generally* notifying participants of research results, you may consider adding it here. Sample text appears below.

However, you can choose to get a newsletter that will tell you about the research studies we are doing. This newsletter will not announce your results or anyone else’s, but it will tell you what we are learning about **[specify condition]**. We also hope to publish what we learn in medical journals.

 **PLEASE NOTE**: If timely and clinically useful medical information is expected, the answer to the question whether results of the research will be returned to the participant must be “yes.” This will require: (1) a different discussion with potential participants (i.e., what they want to know or do not want to know about your finding and when); (2) a consideration of the investigator’s “duty to warn” if findings warrant, and (3) a review of research facility capabilities (i.e., is the laboratory certified); as well as (4) additional language and options in the consent document. Please contact the IRB office to discuss further if dissemination of medical information is expected.

**What are the costs to me to take part in the research [tissue OR data] bank?**

**Instruction:** Explain in plain language what the costs to participate will be. Address both the (1) cost to the participant for collection; and (2) storage of their samples and research on those samples. Sample language appears below.

Collection of **[Samples AND/OR Information]**

* If your **[samples and]** information were collected by the research **[tissue OR data]** bank specifically for this research, there is no cost to you for the procedures of collection.
* If medical care you received, unrelated to this research, resulted in the collection of your **[samples and]** information, the medical care **[and tissue collection procedures]** will be billed as usual to you and your health insurance company or other third-party payers. Contact **[name and telephone number]** if you have questions about the costs of your medical care.

**[Samples and]** Information Storage and Research Activities on Them

* There is no cost to you to have your **[samples and]** information in the research **[tissue or data]** bank or for the research using your **[samples and]** information.

**Will I be paid for providing my [samples and]** information**?**

**Instruction:** Please list any compensation and the schedule of such payments, if any. Be specific. If no compensation will be provided, consider the following sample text.

You will not be paid to participate. Your **[sample and]** information will be used only for research purposes and will not be sold for profit. It is possible that some of the research conducted using your **[samples and]** information may lead to the development of new medical tests and techniques, new drugs or other commercial products. Should this occur, there is no plan to provide you with any part of the profits generated from such products.

**Can I still get medical care if I do not take part in this research [tissue OR data] bank or if I stop taking part?**

Yes. Your decision to participate or not to participate does not affect your relationship with the study staff, your medical care, or any benefits to which you are otherwise entitled. Taking part in the research is up to you. You can decide not to allow your **[samples and]** information to be stored in the research **[tissue OR data]** bank. If you decide to participate now, you can change your mind and withdraw from participation later.

**Whom do I call to ask questions about the research [tissue OR data] bank?**

You may ask more questions about the research **[tissue OR data]** bank at any time. The staff is available to answer your questions about the research, your participation in it, or if you feel you have suffered a research –related injury. They may be contacted at **[telephone #]**. The best time to reach them is **[specify when staff are available, e.g. M-F, 9-5]**. You may also contact the Principal Investigator whose name, address and telephone number are listed on the first page of this consent form.

**Whom do I call to ask questions about my rights as a research subject?**

You may ask more questions about your rights as a research subject at any time. The Rutgers IRB Administrator is available to answer your questions. She or he may be contacted at **[insert the address and telephone number of the appropriate Rutgers campus IRB office]**. The best time to reach them in person is Monday through Friday, 8:30am through 4:30p. Otherwise, call any time to leave a voice message for them.

**Do I have to sign this form?**

Your participation in this research is voluntary.

* If you **do not** want to participate in this research or do not want to authorize use of your personal or private health information, do not sign this consent form.
* If you **do** want to participate in this research and do want to authorize use of your personal or private health information, you must sign this consent form to do so.

Your decision to participate or not to participate in the research does not affect your relationship with the study staff, your medical care, or any benefits or rights to which you are otherwise entitled.

**AUTHORIZATION (PERMISSION) TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES**

**Instruction:** For studies involving the use of protected health information you **MUST** include the following mandatory HIPAA authorization section. While much of the information in this section is redundant to what you have outlined earlier in the consent document, you must repeat it here. Fill in the blanks were appropriate. If the study does not involve use of protected health information, please delete this entire section. If you are unclear what constitutes protected health information, go back to Section II of the instructions to investigators where you will find the definitions of “personal identifiers” and “protected health information.”

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization (permission). If you sign this consent form, it will provide that authorization. The next few paragraphs tell you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization and informed consent form as required or allowed by law. Please read this authorization section and the consent form carefully. Ask questions if anything is not understandable to you.

**What is the purpose of this research and how will my health information be utilized in the Research [Tissue OR Data] Bank?**

**Instruction:** Provide a description of the study, such as its purpose, and describe how the individual’s health information will generally be used in the study, including publication. If this is a clinical trial, also explain that the information in some form will be submitted to the sponsor and the FDA. Feel free to copy relevant text from other parts of the consent document and paste it here.

**Do I have to sign this authorization form?**

You do not have to sign this authorization form. But if you do not, you will not be able to participate in the research study. **[If the study includes any treatment, add the following: “,including receiving any research-related treatment.”]** Signing the form is not a condition for receiving any medical care outside the study.

**If I sign, can I revoke my authorization or withdraw my information later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your information. Therefore, you should be aware that the researchers may continue to use and disclose the health information that was provided before you withdrew your authorization if necessary to maintain integrity of the research or if the data had already been stripped of all identifiers.

If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you may do so in writing by contacting **[insert: investigator’s name, address, and contact information].**

**What personal information will be used or disclosed?**

**Instruction:** List or describe any and all medical information collected from or about the subject in connection with this study. For example: all information in a medical record, certain information indicating or relating to a particular medical condition, blood and other tissue samples and related records, physical examination, x-rays, MRI’s etc.)

Your health information related to this study may be used or disclosed in connection with this research study, including but not limited to:

**Who may use or disclose the information?**

**Instruction:** Please add to the list every other class of persons or organization affiliated with Rutgers (for example, the research team, the study coordinators, etc.) who might need to use and/or disclose the participant’s information in connection with this study.

The following parties are authorized to use and/or disclose your health information in connection with this research study:

* The Rutgers-Institutional Review Board (a committee that independently reviews and approves Rutgers research studies)
* Other Rutgers officials responsible to oversee good conduct in research

**Who may receive and use the information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

* The Office for Human Research Protections in the U.S. Department of Health and Human Services

**Instruction:** Please add to the list every other class of persons or organization not affiliated with Rutgers (for example, a sponsor, a data safety monitoring board, collaborators at other institutions, outside data analysts, the National Institutes of Health, the Food and Drug Administration, etc.) to whom the participant’s information might be disclosed.

Your information may be re-disclosed (shared) by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**

**Instruction:** List a specific date on which the authorization will expire, e.g., “expires on December 31, 2015.” If a participant’s authorization will never expire, state so. If you are uncertain as when the authorization will expire, you may say, “There is no set date at which your authorization will expire. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.”

Your authorization for the use and/or disclosure of your health information will expire **[specify]**.

**Will access to my medical record be limited during the study?**

**Instruction:** Include the following provision if the research involves treatment. If not, delete this subheading. **Please note**: As a general rule, Research Data Banks do not involve treatment. If that is the case with your research, delete this section.

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.

**AGREEMENT TO PARTICIPATE**

**Consent for Myself:**

I have read this form, or it has been read to me, and I understand what has been discussed. My questions about the research **[tissue OR data]** bank and this consent form have been answered to my satisfaction.

I give my consent to take part in this research and agree to allow my **[samples and]** information to be used and shared as described above.

Participant’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (please print your name)

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Consent for My Child or as the Legal Guardian of a Child:**

I give my consent for my child or for a child for whom I am a guardian to take part in this research and agree to allow his or her **[samples and]** information to be used and shared as described above.

Participant Child’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (please print his or her name)

Parent or Legal Guardian’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (please print your name)

Parent/Guardian Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Investigator or Person Authorized to Obtain Participant’s Consent:**

To the best of my ability, I have explained and discussed the operations of the research **[tissue OR data]** bank included all of the information contained in this consent document. All questions of the participant and those of his or her legal guardian have been accurately answered.

Name of Investigator or Person Obtaining Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (please print your name)

Title of Person Obtaining Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (please list your title/role in this research)

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Instruction: PLEASE NOTE:**

**CONSENT ON BEHALF OF CHILDREN**: When children reach 18 years of age they must re-consent for the continued storage and use of their biological materials and/or personal data. You must have SOPs that outline your re-consent process at age of majority if children will be participating in this research tissue/data bank.

**SURROGATE CONSENT:** Human biological materials and personal data from individuals who lack capacity to consent for their own donation to a research tissue or data bank may not be included until statutory requirements are met and appropriate consent procedures are completed and submitted for review (see Rutgers “Guidelines for Surrogate Consent” found at <https://orra.rutgers.edu/hspp-toolkit> )

**FOREIGN-LANGUAGE CONSENTS**

If five or more potential participants speak/read a language other than English, the consent document must be translated into that language. Because tissue and/or data banks, by their very definition, will exist over an extended period of time and which usefulness is enhanced by broad participation, HSPP strongly encourages translations of the consent document at the outset of establishing tissue and/or data banks. Rutgers’s policy on consent translations is found at (under construction). A current list of approved translation services may be found at <http://procure.rutgers.edu/>.