**Instructions**

To stand out both on your computer screen and in black/white copies, instructions are in bold, italic, and blue type.

Instructions are in boxes and will be deleted by the IRB in the final consent.

**IRB-required template language is in black type and should not be changed.**

Rarely, changes to the required language may be necessary. To petition for a change in required language, submit proposed changes with justification to the IRB office at irbadmin@campbell.edu.

Sample language, which can be used, modified, or deleted as appropriate for your project, is in blue type. **Please maintain the blue color to distinguish your project-specific information from the required template language.**

⇒ Arrows are used to show alternative choices. In the final consent, arrows can be deleted and the usual margin maintained.

*This template is for* ***banking*** *projects: the collection of information and/or biospecimens for future unspecified research, I.e., any purpose other than those specified in the project for which it was obtained.*

*Additional modules for special cases may be obtained from the IRB Office.*

*These modules can be inserted into the appropriate project-specific text boxes.*

**Campbell University**

**INTRODUCTION TO THE INFORMED CONSENT**

<Project Title>

<Principal Investigator>

<Department>

<Telephone Number>

<Campbell University>

<P.O. Box <Number>

<Buies Creek NC 27506>

We are asking your permission to save some of your <health information/specify biospecimen(s)> for research in the future. This form tells you what we would like to do and possible risks. If there is anything you do not understand, please ask questions. Then you can decide if you want to give your permission or not.

**Overview**

**Purpose:** This banking project is being done to <…insert brief purpose.>

**Procedures or Activities:** <You may insert a brief introduction. E.g., There are two groups in this project. You will be enrolled in one of the two groups based on …> <If this bank is associated with a local project indicate such.

**<Procedures/ Activities/Visits that will occur at various visits: (if bank is associated with local project include procedures/activities that are being banked)**

 **Invasive Procedures/Activities**

 Briefly list most invasive and intensive procedures.

 **Non-Invasive Procedures/Activities**

 Briefly list less invasive procedures.>>

 General information on data collection or types of data collected.

**Time Commitment:**

* Your <health information/specify biospecimen(s)>will be kept for an indefinite amount of time.

**Primary risks:** This is a brief list of the most common risks associated with the banking research. <Explain risks here, see risk section below for examples.>

**Benefits:** There is no benefit to you for participating in this bank.

**My Other Options:** You do not have to join this bank. Your other options may include joining a different bank or not joining any bank.

The first page of this document includes a summary (key information) of this project to help the participant decide whether or not to participate. Key Information should only be one page in length. Detailed information is provided after the summary.

**Key Information**

**CONSENT TO PARTICIPATE IN RESEARCH**

**What is banking and what is a bank?**

“Banking” is storing of health information and/or blood or tissue for future research. A “bank” is the place where it is stored.

**Why is this banking being done?**

<Principal Investigator name> wants your permission to bank your < health information/specify biospecimen(s)> for future research. We would like you to take part in this bank because you <are/have a specific disease or condition, etc.>. In the future, other doctors and scientists at this institution and other institutions may use your < health information/specify biospecimen(s)> to learn about many different diseases or conditions.

***If banking biospecimen(s), insert this paragraph; otherwise delete:***

If you agree to allow your~~,~~ specify biospecimen(s)> to be banked, there is a chance that it/they may be used to study genetic material. Genetic material, or genes, are made up of DNA, and contain all the information which is passed on in families. These projects may look at differences in genetic material that might influence the likelihood of developing a certain disease, or of responding to specific drugs or treatment.

**Do I have to bank my <health information/specify biospecimen(s)>?**

You are free to say yes or no. Your decision will not change your current or future status or your current or future health care.

***Insert appropriate statement if there is a “main project”; otherwise delete.***

* [No matter what you decide, you can still take part in the main project, <Original Project Title>].
* [If you decide not to bank your <health information/specify biospecimen(s)> you cannot take part in the main project, <Original Project Title>].

**What samples will be banked?**

***Delete this entire section and header if no biospecimen(s) are collected. Insert the appropriate statement(s) if biospecimens are collected***

* <PI name> will bank your leftover <specify biospecimen(s) from [specify procedure… [This procedure was recommended by your doctor as part of your routine care for your condition and is not part of the research].
* <PI name> will take [an / \_\_(number) additional sample(s) of your <specify biospecimen(s)> during [specify procedure] [from the main project] and bank [it / them. [This procedure is part of your routine care and not part of the research].
* <PI name> will bank your <specify biospecimen(s)> form [specify procedure] only for the purpose of banking.

The protected health information originates from <insert institution/clinic/site>.

***Delete this entire section and header if no health information will be collected or used. List here the types of information to be collected or used for the research, including the time period form which they are collected.***

**What Health Information will be banked?**

To be in this bank, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the bank. This information may come from questions we ask, forms we ask you to fill out, or from your medical record, as described below. We will only collect and use information needed for the bank.

The protected health information originates from <insert institution/clinic/site>.

**The health information we will collect and bank is:**

***List here the types of information to be collected or used for the research, including the time period from which they are collected.***

* [Medical records of the care you received during the main project].
* [Medical records dating from when you join the main project until you die].
* [CT scan, MRI, ultra-sound, radiographs (x-rays), images, etc.]

**Where will my <health information/specify biospecimen(s)> be banked?**

<PI name> will bank your <academic information, health information/specify biospecimen(s)> at <Campbell University, other outside institution or laboratory> along with <information and/or biospecimen(s)> of many other people.

***Include only if applicable to the project, otherwise delete header and paragraph***

**Are there any special instructions?**

[You should not take ibuprofen while you are in this project].

**What are the risks or problems I can expect?**

***Choose one, only if applicable to the project, otherwise delete***

**Are there any physical risks?**

***If biospecimen(s) to be collected for the bank would be otherwise discarded from a clinically-indicated procedure, then no physical risks are part of the bank itself.***

This procedure was recommended by your doctor as part of your routine care for your condition. There is no extra physical risk to you as part of the bank.

***If more biospecimen will be collected for the bank than is required for clinical purposes, describe the amount, procedures, and physical risks in obtaining the biospecimen.***

<Principal Investigator name> will bank [an additional amount of, specify biospecimen(s). from [another procedure]. [Describe extra physical risks incurred for biospecimen(s) to be banked, if any.] [The amount of blood taken will still be within safety limits for you.]

**[Describe amount and collection procedure]. [This is an extra procedure]. [describe extra physical risks incurred for biospecimen to be banked, if any.] [The amount of blood taken will still be within safety limits for you.]**

***If more biospecimen will be collected only for banking, describe the amount, procedures, and physical risks in obtaining the biospecimen:***

**Are there any risks to confidentiality?**

***If bank is at Campbell University and information/biospecimen(s) is IDENTIFIED, describe the risks to confidentiality:***

***Choose one of the following paragraphs and delete the others***

Your <health information/specify biospecimen(s)> will be banked at Campbell University with personal details. One risk of taking part in research is that more people will handle your personal health information. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you. [If some records include genetic information, it is against federal law (GINA) for health insurance companies to deny health insurance, or large employers to deny jobs, based on you genetic information. But the same law does not protect your ability to get disability, life, or long-term care insurance. If you have questions, you can talk to the research investigator about whether this could apply to you.]

***If bank is at Campbell University and information/biospecimen(s) is CODED, describe the risks to confidentiality:***

Your <health information/specify biospecimen(s)> bill be banked at Campbell University with a code so that only <Principal Investigator name> [and authorized members of the research team] can link the information with your personal identifiers. One risk of taking part in research is that more people will handle your personal information. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. [If some records include genetic information, it is against federal law (GINA) for health insurance companies to deny health insurance, or large employers to deny jobs, based on you genetic information. But the same law does not protect your ability to get disability, life, or long-term care insurance. If you have questions, you can talk to the research investigator about whether this could apply to you.]

***If bank is at Campbell University and information/biospecimen(s) is ANONYMOUS, describe risks to confidentiality.***

Your <health information/specify biospecimen(s)> will be banked with no personal identifiers so that no one will know that it came from you.

Your <health information/specify biospecimen(s)> bill be sent to <name of bank/laboratory/repository> with some personal details. Personal identifiers such as dates, initials, or academic/medical numbers could identify you. It is possible that that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you. [If some records include genetic information, it is against federal law (GINA) for health insurance companies to deny health insurance, or large employers to deny jobs, based on you genetic information. But the same law does not protect your ability to get disability, life, or long-term care insurance. If you have questions, you can talk to the research investigator about whether this could apply to you.]

***If bank is ELSEWHERE, and information/biospecimen(s) is sent IDENTIFIED, describe the risks to confidentiality.***

***If bank is ELSEWHERE, and health information/biospecimen(s) is sent CODED, and:***

* ***If a written agreement is submitted to the IRB confirming that subjects’ identities will never be revealed to the distant bank, the “ANONYMOUS” text (above) can be used.***
* ***If no written agreement is present, the information/biospecimen(s) is considered identified, and “IDENTIFIED” text (above) must be used.***

***If bank is ELSEWHERE, and information/biospecimen(s) is sent ANONYMOUS, describe the risk to confidentiality:***

Your <health information/specify biospecimen(s)> bill be sent to <name of bank/laboratory, repository> with no personal details, so that the researcher <name of bank/laboratory/repository> will not know who you are.

**Are there benefits of banking my <health information/specify biospecimen(s)>?**

There is no direct benefit to you. Other people might benefit if researcher learn more by using your banked <health information/specify biospecimen(s)>.

**What are the costs of banking my <health information/specify biospecimen(s)>?**

***Outline clearly the activities/costs to be billed to subject/subject’s insurance company, and those to be paid by sponsor/Investigator, if any. Campbell University cannot be identified as a funding source unless approved by ORSP. This sample can be modified:***

There are not costs to you or your insurance company for any of the procedures in this [banking / banking part of the] project, which are [list procedures such as blood draw, … ]. If you have question regarding project costs, please contact Dr. <insert name>.

***If harm language is included below, include the following. If not delete.***

If you participate in this research bank, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

**Will I be paid for banking my <health information/specify biospecimen(s)>?**

***Describe the amount to be paid and payment schedule, such as, if payment is pro-rated. Examples to be modified:***

* There is no payment for being in this project [but we will give you a gift certification for ….>.
* You will receive [$] for each visit. [Describe payment schedule and total possible payment]. To pay you, we need your social security number. [**if paid through Campbell University**] any payment may be reportable as income on your taxes.

Your < health information/specify biospecimen(s)> will be used only for research <Principal Investigator name> and <name of bank/laboratory/repository> will not sell any of it. Sponsor, other researchers, or research companies may patent or sell products, discoveries and data or information that result from this research. Neither Sponsor nor <Principal Investigator name> will pay you if this happens. You will not receive any payment or commercial rights for products, data, discoveries, or materials gained or produced form your <health information/specify biospecimen(s)>.

***This section is only required for projects involving greater than minimal risk. However, if this bank involves a medical intervention, it is recommended that this section be included.***

**What happens if I am injured because I took part in the bank?**

Enter our harm language.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: <Principal Investigator name>, <telephone number>.

**Nothing in this consent form affects any affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.**

**Who can answer my questions about the bank?**

* If you have more questions about this bank at any time, you can call <Principal Investigator name> at <telephone number>.
* If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the Campbell University Research Subject Advocate, in the IRB Office at 910-893-7780.

***HIPPA Authorization Language. Please insert the following paragraphs, if using Health Information or Biospecimen(s):***

**Who will see my health information/biospecimen(s)?**

The only Campbell University employees are allowed to handle your health information are those on the research team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure Campbell University’s rules are followed.

***Delete this paragraph if no one outside Campbell University will access identified information.***

The research team may share your information with people who don’t work at Campbell University because they planned, pay for, or work with us on this bank. The federal Privacy Rule may no longer protect your health information once it leaves Campbell University. For this bank we plan to share this information with those doctors, researchers or government representatives working with us on this bank at the institutions or companies listed here:

***Here list (name), institution, city and state for each sponsor or collaborator needing access to identified data or source records. It is NOT necessary to list Sponsors who do not need access to data or source records.***

[Industry Sponsor, City, State] ***(Delete if not applicable)***

[Multi-site Coordinating Center, City, State] ***(Delete if not applicable)***

[Dr. X, Y University, City, State] ***(Delete if not applicable)***

***Insert the following paragraph if applicable:***

If we share your, <health information/biospecimen(s)> with other research groups outside of Campbell University, your personal identifiers will be removed so that no one will know that it came from you.

***The following paragraph is required if information and/or biospecimens are being collected as part of the bank.***

We will not use your personal health information for a different project without your permission of the permission of an Institutional Review Board (IRB). Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be present that identifies you.

**How long will my,** **<health information/specify biospecimen(s)> be banked?**

***Insert the appropriate statement***

* Your <health information/specify biospecimen(s)> will be banked for [insert number of] years [after the project is over, which we expect will be [insert year]].
* The purpose of the bank is to answer questions in the future, so we expect to keep you <health information/specify biospecimen(s)> for a long time, maybe forever.

**Can I remove my <health information/specify biospecimen(s)> once it is banked?**

***Insert if bank is at Campbell University and health information/biospecimen(s) is identified or coded.***

Your <health information/specify biospecimen(s)> is/are banked at Campbell University. If it is still identified as yours, you can have it removed or destroyed by contacting <Principal Investigator name> in writing at specify address.

***Insert if bank is elsewhere, and heath information/biospecimen(s) is identified (by identifiers, codes or double coding):***

Your <health information/specify biospecimen(s)> is/are banked outside of Campbell University. You can contact <Principal Investigator name> in writing at specify address and ask to have your <health information/specify biospecimen(s)> removed from the bank or destroyed. [Because your sample is identified by a code / double-code, it can be destroyed even though the bank does not know your identity.] Since your <health information/specify biospecimen(s)> is at <name of bank/laboratory/repository> we cannot guarantee that this will happen.

***Insert if health information/biospecimen(s) is not identified:***

No. Your <health information/specify biospecimen(s)> is/are banked outside of Campbell University and is no longer identified as yours, so it is not possible to remove it from the bank.

**CONSENT TO PARTICIPATE IN THE PROJECT**

By signing my name below, I confirm the following:

* I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
* The project’s purpose, procedures, risks and possible benefits have been explained to me.
* I agree to let the project team use and share the health information and other information gathered for this project.
* I voluntarily agree to participate in this research project. I agree to follow the project procedures as directed. I have been told that I can stop at any time.
* At any time, I can ask the bank to stop collecting <health information/specify biospecimen(s)>, and aske the bank to delete/destroy all my <health information/specify biospecimen(s)>, if it is still identified as mine.

**IMPORTANT:** Your will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

***Signature line instructions:***

*Generally, the subject’s signature is sufficient. Thus, the following signature lines are* ***optional*** *to include: Legally Authorized Representative, Witness, Principal Investigator or designated representative. These should only be included when the Investigator chooses to include them, the project involves certain subject populations, or when required by the Sponsor.*

***Date or Date & Time: Time is optional to include (suggested if doing same day procedures); if included, it must be completed by each signer***.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Subject’s Name** *please print* | **Subject’s Signature** | **Date** OR **Date/Time** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Legally Authorized Representative** (if applicable) *please print* | **Signature of Leally Authorized Representative** | **Date** |
|  |  |  |
| **Name of Subject***please print* | **Relationship to Subject** (*e.g., Court-appointed guardian, healthcare power of attorney, next of kin)* |
|  |  |
| **Name of Witness** (if applicable) *please print* (for short form consent process, or consent of blind or illiterate subject) | **Signature of Witness** | **Date** |
| **Rationale for Use of Witness**[ ]  Subject has limited/no literacy[ ]  Subject has limited English proficiency[ ]  Subject has limited/no vision | [ ]  Sponsor requirement[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

*\*A member of the project team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. In all research project protocol, the Principal Investigator is responsible and accountable for the project.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **\*Name of person discussing/obtaining consent** *please print* | **Signature of person discussing/obtaining consent** | **Date** |