**Instructions**

To stand out both on your computer screen and in black/white copies, instructions are in bold, italic, and blue type. Instructions boxes in orange are additional elements to be used when appropriate and these sections may be deleted if not applicable to your research project.

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

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 minimal risk projects (surveys, interviews, focus groups or observation) or minimal risk interventions/interactions (community or educational interventions)*

*This consent/assent template can be used for both consent of parent(s) and assent of minors age 14-17 years old. For minors younger than 14, a separate assent form should be used.*

*According to North Carolina State Law, minors are persons under the age of eighteen. Investigators overseeing research outside the State of North Carolina should be aware that age of majority varies according to State Law.*

**Campbell University**

**INTRODUCTION TO THE INFORMED CONSENT**

<Project Title>

<Principal Investigator>

<Department>

<Telephone Number>

<Campbell University>

<P.O. Box <Number>

<Buies Creek NC 27506>

**Subject:** You are invited to take part in this research project. This form tells you why this research project is being done, what will happen in the research project, and the possible risks and benefits to you. If there is anything you do not understand, please ask questions. Then you can decide if you want to join this project or not. If you are under the age of 18, your parent or guardian also needs to give their permission for you to join this project.

**Parent/Guardian**: Your child is invited to take part in this research. This form tells you why this project is being done, what will happen in the project, and possible risks and benefits to your child. If there is anything you do not understand please ask questions. Then you can decide if you want your child to join this project or not. The word **“you”** in this form refers to your child. The following disclosure is made to give you an opportunity to decide if this relationship will affect your willing ness to participate in this research project.

**Overview**

**Purpose:** This research 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 …]

**[Procedures/ Activities/Visits that will occur at various visits:**

**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:**

* You will be in this project for [estimate length of time].

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

**Benefits:**

⇒ This project will not help you, but we hope the information from this project will help us develop a better [treatment / understanding] for [insert] or help us provide better health services for [insert]. OR

⇒ This project may or may not help you, but we hope the information from this project will help us develop a [better treatment / understanding] for [insert] or help us provide better health services for [insert.]

**My Other Options:** You do not have to join this research project. You may ask the Principal Investigator or project team member if there are any other options available.

The first page of this document includes an overview (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.

**CONSENT TO PARTICIPATE IN RESEARCH**

**Why are we asking you to participate?**

***Describe reason(s) for subject participation, such as diagnosis and eligibility.***

You are being invited to participate in this research because [“you have been diagnosed with…” or “of your back pain, you may be eligible for an educational program…”, fill in the circumstance or condition that makes participants eligible for the research].

A total of about [xx] people are expected to participate in this research.

***List any funding source for the project, including departmental or internal funding, if applicable, otherwise delete:***

[Principal Investigator name and/or *Institution Name]* will be paid by the Sponsor, [insert sponsor name] for conducting this research project.

***If a financial conflict of interest needs to be explained, state it here, otherwise delete:***

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willing ness to participate in this research project: [insert disclosure].

**Do I have to participate?**

You can decide whether to take part in this research or not. You are free to say yes or no. Your participation is voluntary. [If you do not agree to join, or if you leave the project, you will not be penalized or lose any benefits that you had before starting the research project.] Even if you join this project, you do not have to stay in it. You may stop at any time. You may take as much time as you need to make your choice.

**Why is the project being done?**

***Describe the purpose of the research. You may phase the purpose in a way lay people will understand, but do not be evasive about the real purpose.***

The purpose of this project is [insert text here].

**How long will the research last and what will I need to do?**

***Modify as needed regarding subject’s involvement.***

* You will be in the research project for about [estimate length of time of subject’s involvement].
* After your visit(s) to the health facility is/are finished, we want to keep in touch with you to follow your health over time. We will [telephone you / ask you to come into the health facility] [once a month, one a year,] [for the next year] and ask about [insert information].

**What will happen if I participate in this project?**

***Describe the project procedures clearly and simply.***

* ***Begin with screening procedures, if any.***
* ***Describe the groups, if it applies.***
* ***Include the duration of each visit or procedure.***
* ***Identification of any procedures , which are experimental.***

[Insert text here.]

***Include this statement for research that involves randomization. Otherwise delete.***

⇒ The treatment you get will be chosen by change, like flipping a coin. Neither you nor the project doctor will choose what [treatment/intervention] you receive. You will have a(n) [equal / one in three/ etc.] chance of being given either treatment.

***Include one of the following statements, if applicable. Otherwise delete.***

⇒ [For double-blinded research, add] Neither you nor the project doctor will know which treatment you are getting.

⇒ [For single blinded research, add]You will not be told which treatment you are getting, however your project doctor will know.

***Include this statement for research that involves audio, video or imaging consent module, if applicable, otherwise delete***

[Describe the setting, duration and procedures of recording session, and use, storage and security of recordings]

***For example:***

Parts of the recording of the session will be transcribed to written form, without identifying the speakers. The recording will be erased when all data from it have been reviewed and coded, not later than 7 days after the session.

Initial either 1 or 2:

1. \_\_\_\_\_\_\_ I do not want to be [audio / video] recorded in this project. This means that I cannot participate in the study.

**Stop here** and speak to [Principal Investigator name]. Do not sign this form.

2 \_\_\_\_\_\_\_ I agree to be [audio / video] recorded in this project.

Or

1. \_\_\_\_\_\_\_ I do not want to be [audio / video] recorded in the project. I understand I still can participate in other parts of the project.
2. \_\_\_\_\_\_\_ I agree to be [audio / video] recorded in this project.

**If research involves genetic testing or whole genome sequencing of biospecimens, insert genetic module here.**

**What risks or problems can I expect from the project?**

We watch everyone in the project for unexpected problems [side effects]. **You need to tell the [Principal investigator/doctor name] or a member of the project team immediately if you experience any problems [or become too upset]**.

***Describe the risks of any project procedures. Some examples are listed below:***

⇒ **Questionnaires:** You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. [If you become upset, please let us know and we can provide names of counselors…**OR** give you information about individuals who may be able to help you…]

⇒ **Blood Draw:** The side effects that you might experience as a consequence of donating a blood sample for this project include possible discomfort and bruising at the needle entry site. Rare complications of any venipuncture (drawing blood from a vein) include fainting, arterial puncture, peripheral nerve injury, local infection, and local blood clot. There may be other unanticipated risks, but every precaution will be taken to assure your personal safety and to minimize discomfort. The person drawing your blood will observe you for side effects, but please inform him or her if you experience any discomfort or feel faint.

Another risk may be loss of confidentiality. Every effort will be made to keep your project records confidential but we cannot guarantee it. If you have questions, you can talk to the principal investigator.

**Are there any benefits to taking part in the project?**

***Choose one of the options and modify.***

⇒ This project will not help you, but we hope the information from this project will help us develop a [better treatment / understanding] for [insert] or help us provide better health services for [insert].

⇒ This project may or may not help you, but we hope the information from this project will help us develop a [better treatment / understanding] for [insert] or help us provide better health services for [insert].

**Can I stop being in the project?**

***Include if there are potential adverse consequences to withdrawing from the research. Otherwise, delete***

You can leave the research project at any time.

[If you decide to leave the project, please let the project team know.]

Choosing not to be in this project or to stop being in this project will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this project will not negatively affect your right to any present or future medical treatment.

***Student or employee participation in research, if applicable, otherwise delete.***

Taking part in this research is not a part of your job duties or student requirements and refusing will not affect your job or student status. You will not be offered or receive a special job related or academic consideration if you take part in this research.

[The project investigator may stop your participation in the project at any time for any reason without your consent. They will tell you if this happens.]

[Describe what will happen to data collected to the point of withdrawal]

**Are there any costs to being in the project?**

***Outline clearly the activities/costs to be billed to subject / subject’s insurance company, and those to be paid by sponsor/Investigator. Choose one of these options and modify:***

⇒ There are no costs to you for participation in this project. If you have questions regarding project costs, please contact [Principal Investigator name].

⇒ The costs to you of being in the project are [list as applicable]. If you have questions regarding project costs, please contact [Principal Investigator name].

* *Include only if harm language is inserted below, otherwise delete*: If you participate in this research, 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.

**Include only if appropriate, otherwise delete the following question & paragraph.**

**Will I be paid for being in the project?**

***Describe the amount to be paid, method of payment and payment schedule, or state if none. Choose the appropriate options and modify:***

⇒ There is no payment for being in this project [but we will give you a parking voucher for free parking with every visit].

⇒ You will be paid [$] or a [$] gift certificate after 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.

**Include this language if subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit, if appropriate, otherwise delete.**

⇒ Sponsor, other researchers, or research companies may patent or sell products, discoveries and data or information that result from this research. Neither Sponsor nor [PrincipaI Investigator name] will be you if this happens. You will not receive any payment or commercial rights for products, data, discoveries, or materials gained or produced from your [health information / specify biospecimens].

**Include only if project required by regulations, otherwise delete the following question & paragraph.**

**What other healthcare choices do I have?**

Instead of being in this research project, your choices include:

⇒ [List alternative procedures. For clinical trials describe the options that you would normally offer a patient. If applicable, include supportive care as an option.]

OR

⇒ [Include if there are no alternatives other than participating.] Your alternative to participating in this research project is to not participate.

**Include only if new information (ex. Risks, project results/outcomes, etc.) will be given to subjects, otherwise delete the entire section. Examples are listed below:**

**Will I be given new information about the project?**

⇒ If we learn any important new information [about the intervention] that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.

⇒ After the project has been completed, we will notify you of the results.

***If the results of any procedure or test performed as part of this research may yield clinically relevant results and will be shared with the subject, the following must be inserted:***

When research [data/biospecimens/images/etc.] [is/are] collected and analyzed, there is the change of finding something clinically relevant. There may be benefits to learning such results such as early detection and treatment of a medical condition but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

In this project, you will be informed of any findings of possible clinical significance that may be discovered during review of results from your research [data/biospecimens/images/etc.]. The results of your research [data/biospecimens/images/etc.] [will/will not] be placed in your medical record.

[Please include any additional conductions for disclosure.]

***If the results of any procedure or test performed as part of this research may yield clinically relevant results and will NOT be shared with the subject, the following must be inserted:***

The results from the [data/biospecimens/images/etc.] we collect in this research project the same qualify as what you would receive as part of your health care, so you will not be informed of any clinically relevant research findings. The results of your research [data/biospecimens/images/etc.] [will/will not] be placed in your medical record.

***Insert harm language module. This section is only required for projects involving greater than minimal risk.***

***Institutional-specific language regarding compensation for injury may be included instead of Campbell University template language. Please note – the proposed language is subject to review and requests for changes by the Campbell IRB Office must be requested.***

***The following paragraph is required if identified data and/or biospecimens are being collected as part of the research, otherwise delete. This section may also be deleted, if it will be included below in HIPAA authorization.***

**How will my [health information/biospecimens] be used?**

Only the [Private Investigator name] and authorized staff will have access to your identified health information [and/or biospecimens]. Once all personal identification is removed from your health [and/or biospecimens] information, the information [and/or biospecimens] the information [may be/may not] used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be present in public talks or written articles, but no information will be presented that identifies you.

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

* If you have more questions about this project at any time, you can call the [Principal Investigator name] at [phone number].
* If you have questions about you rights as a project participant, want to report any problems or complaints, obtain information about the project, offer input, or feel you have been injured, you can call the Research Subject Advocate at 910-893-7780.

***Delete the following section if no identified health information (PHI) will be collected about the subject or you will be using a separate HIPAA Authorization.***

**Permission to collect, use and share Personal Health Information (PHI)/ HIPAA Authorization**

**What health information will be collected and used for this project?**

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

The health information we will collect and use for this project is:

***List here the specific types of health information to be collected or used for the research project, including the time period from which they are collected. Examples include:***

***If the any of the health information to be collected comes from care or services received at a Campbell University clinic or site, please include the following statement. If not, please delete.***

⇒ Health information collected during this project, such as questionnaires

⇒ [Medical records dating from when you join this project until you die]

⇒ [CT scan taken when you were first diagnosed with <specific disease/condition>]

**Who will see the health information collected for this project?**

The only people allowed to handle your health information are those on the project team at Campbell University [and at <Community Organization>], those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the Campbell University rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

***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. Delete the following section, if not applicable.***

***Include the following paragraph, if harm language was included above. Otherwise delete.***

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

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

[CRO, City, State)] ***Delete if not applicable***

[Multisite coordinating Center, City, State] ***Delete if not applicable***

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

***If research project involvement does not require any clinical tests or procedures at Campbell, and no research information would appear in any Campbell medical record, the following paragraph can be deleted.***

We may record your research information, including results, procedures or questionnaires done for research, in your Campbell University medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

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

We will not use your personal health information for a different project without your permission or the permission of a research review board (IRB). Once all personal identification is removed from your health [and/or biospecimens] information, the information [and/or biospecimens] may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be present in public talks or written articles, but no information will be presented that identifies you.

**What are the risks of sharing this health information?**

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The project team will make every effort to protect the information and keep it confidential, but it is possible than an unauthorized person might see it. If you have questions, you can talk to the principal investigator about whether this could apply to you.

**How long will you keep the health information for this project?**

If you sign this form, we plan to keep your information [for xx years / for 3 years after the research project ends / without any end-date] in case we need to check it again for this project.

**Can I cancel my permission to share this health information?**

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to [Principal Investigator name] at [specify address]. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we already collected.

***Insert this section if access to records will be prohibited***

**Access to records**

You may not be able to see, or copy, your project-related health information until after the project has been completed; otherwise, it could affect the research project.

**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.

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***.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Minor Subject** *please print* | **Signature of Minor Subject** | **Date** **OR Date/Time** |
|  |  |  |
| **Name of Parent/Guardian** *please print* | **Signature of Parent/Guardian** | **Date** |
|  |  |  |
| **Name of Witness** (if applicable) *please print* (for short form consent process, or consent of blind or illiterate subject) | **Signature of Witness** | **Date** |
| **Rational for Use of Witness**  Subject has limited/no literacy  Subject has limited English proficiency  Subject has limited/no vision | Sponsor requirement  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
|  |  | |
| **\*Name of person discussing/obtaining consent** *please print* | **Signature of person discussing/obtaining consent** | |

*\*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 Second Parent/Guardian** *please print* | **Signature of Second Parent/Guardian** | **Date** |
| **If the signature of the second parent/guardian cannot be obtained, please indicate the reason:**  Second parent/guardian is deceased  Second parent/guardian is not reasonably available  Second parent/guardian is incompetent  Only one parent/guardian has legal responsibility for the care and custody of the minor  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |