**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.

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 (blood draws, MRI, community or educational interventions)*

*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**

**CONSENT TO PARTICIPATE IN RESEARCH**

Name of Project Subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<Project Title>

<Principal Investigator>

<Department>

<Telephone Number>

<Campbell University>

<P.O. Box <Number>

<Buies Creek NC 27506>

[<Sponsor> is funding the project. OR The National Institute of Health, a government agency, is funding this project. OR There is no funding for this project

[If a financial conflict of interest needs to explained, state 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>.

**[Include if the investigator is also the participant’s treating physician. Otherwise, delete]**

Your doctor, who is also responsible for the research project, [or, if you doctor is also the person responsible for this research project, please note that she/he] is interested in both your clinical care and the conduct of this research project. You have the right to discuss this project with another person who is not part of the research team before deciding whether to participate in the research.

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**

**Why am I being asked to take part in this research project?**

We are asking you to take part in this research project because [Fill in the circumstance or condition that makes participants eligible for the research].

**What should I know about a research project?**

* Someone will explain this research project to you.
* Whether or not you take part is up to you.
* You can choose not to take part.
* You can agree to take part and later change your mind.
* Your decision will not be held against you.
* You can ask all the questions you want before you decide.

**Why is this research being done?**

[(1) Tell the participant the purpose of the research in terms that can be understood by people not in the medical field.

(2) Explain the background of the research problem.

(3) Explain any potential benefits to others.]

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

We expect that you will be in this research project for [insert as hours, days, months, weeks, years, until a certain event].

You will be asked to [include a high-level summary of the procedures that will be done. For example: “You will be given a drug and asked to come in for 3 project visits.” Or “You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.”]

More detailed information about the project procedures can be found under the section, **“What will happen if I participate in this project?”**

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

[This section of the consent document should identify the most important risks, similar to the information that a physician might deliver in the clinical context, tell a patient how sick drugs will make them; but, with a particular emphasis on how those risks are changed by participating in the project.]

More detailed information about the risks of this project can be found under, **“What risks or problems can I expect from the project?”**

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

We cannot promise any benefits to you or others from your taking part in the project. However, possible benefits include [Then describe the potential benefits of participation. First, describe any direct benefits to the participant, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

**What happens if I do not want to be in this research?**

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

[Include if there are alternatives other than participating.] 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.

The rest of this document includes detailed information about this project (in addition to the information listed previously.

**Detailed Information**

**How many people will participate in the research project?**

We expect about <insert number> people here will be in this research project in the entire project [at Campbell University, nationally, internationally].

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

**[In terms that can be understood by people not in the medical field, tell the participant what to expect using lay language and simple terms. Whenever appropriate include the following items (\* are required):**

* A timeline description of the procedures that will be performed. If practical, prepare a timeline chart or schematic to accompany descriptions of procedures and tests for research that require more than one or two steps/visits.\*
* Screening procedures, if applicable.\*
* All devices that will be used, if applicable.\*
* The length and duration of visits and procedures.\*
* The drugs or biologics that will be given to the participant.
* All devices that will be used.
* All hospitalizations, outpatient visits and telephone or written follow-up.
* If blood will be drawn, indicate the amount [in English units] and frequency.
* With whom the participant will interact.
* Where the research will be done.
* When the research will be done.
* List experimental procedures and therapies and identify them as experimental.\*
* How often procedures will be performed.
* What is being performed as part of the research project.
* What is being performed as part of standard care.
* What procedures are part of regular medical care that will be done even if the participant does not take part in the research.
* When applicable, indicate that the participant will be asked to be contacted for future research.
* When applicable describe if audio or video recording any research activities. Include if agreement to be recorded is required for participation or if it is optional.]

 **[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.

⇒ [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.

**[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>. 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.

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

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

**[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. The risks of procedures may be presented in a table form.]**

* Physical risks
* Psychological risks
* Privacy risks
* Confidentiality risks
* Legal risks
* Social risks
* Economic risks
* Group or community risks

Distinguish between the risks presented by participation in the research and the risks associated with any procedures or treatments that would occur regardless of participation in the research. Also, in general, do not include results of animals studies, unless there is no other known risk information and inclusion would aid with understanding. Examples include:]

⇒ **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?**

⇒ 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>>.

**What happens if I do not want to be in this research?**

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

[Include if there are alternatives other than participating.] Instead of being in this research project, your choices include:

⇒ [List alternative procedures. Describe the options that you would normally offer a patient or student.]

OR

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

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

You can leave the research project at any time.

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

**[Insert student or employee participation in research module, 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. He / She 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>.

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

**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, and a gift certificate for…].

⇒ You will be paid [$] 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.]**

⇒ Sponsor, other researchers, or research companies may patent or sell products, discoveries and data or information that result from this research. Neither Sponsor nor <PI> 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>.

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

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

⇒ 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.

Clinically relevant results, including individual results, [will / will not] be disclosed to you. *[If results will be disclosed, describe the conditions for disclosure]*

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

* If you have more questions about this project at any time, you can call <Principal Investigator> 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 IRB Office at 910-893-7780.

**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:]**

⇒ 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.

**[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.]**

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 University, and no research project information would appear in any Campbell University medical record, the following paragraph can be deleted.]**

We may record your research information, including results of tests, procedures or questionnaire done for research in your Campbell 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.

Once all personal identification is removed from your health [and/or biospecimens] information, the information [and/or biospecimens] [may/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. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. 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. 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.

**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***.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **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 Witness** (if applicable) *please print* (for short form consent process, or consent of blind or illiterate subject) | **Signature of Witness** | **Date** |

*\*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** |