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

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

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

**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 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.

**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 be explained, state here, otherwise delete]

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research project:

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

**Key Information**

The following is a short summary of this project to help you decided whether to take part in this research project. Detailed information regarding this project is listed later in this document.

**[The following should be all in one paragraph]**

The purpose of this project is <insert>. You will be asked to [include a brief statement of the procedures that will be done. For example: “You will be asked to complete a survey and a follow-up interview.”]. We expect that you will be in this research project for [hours/days/months/weeks/years, until a certain event]. The primary risk of participation is [insert risk]. The main benefit of participation is [insert if there is a benefit or There is no benefit to you for participating in the research project.].

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

**Detailed 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 (i.e., student, parent) or condition (i.e., age) that makes participants eligible for the research].

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

* Someone will explain this research project to you. [Remove for online consent or any consent that is not in-person.]
* 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 or academic field.

(2) Explain the background of the research problem.

(3) Explain any potential benefits to others.]

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

**[In terms that can be understood by people not in the medical or academic 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.\*
* 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 or practice.
* What procedures are part of regular educational/social practice 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.]

**[Insert 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 the be audio / video recorded in this project. This means that I cannot participate in the study.

**Stop here** and speak to Dr. \_\_\_\_\_\_\_\_\_\_\_. 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.

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

⇒The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the project doctor will choose what treatment 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 the project staff will know.

**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 [principle 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 animal 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 information about individuals who may be able to help you…]

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?**

[Delete this section if there are no benefits that were not state in the Key Information section.]

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 or options. 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?**

Participation in research is voluntary. You can decide to participate or not to participate.

**[Include if there are potential adverse consequences to withdrawing from the research. Otherwise, delete]** If you decide to leave the project, <describe consequences>. If you decide to leave the research 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.

**[Insert student or employee participation in research module, if applicable.]**

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 principal 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 <Principle Investigator>.

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

⇒ 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.

**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.

**[REMOVE THE FOLLOWING PARAGRAPH IF PII IS NOT COLLECTED]**

**Permission to access, collect, use Personal Identified Information (PII)**

**What personal 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 personal 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, as described below. We will only collect and use information needed for the project. We cannot promise complete privacy and confidentiality. Organizations that may inspect and copy your information include the IRB and other representative of this institution. [Add to this list other organizations that may have access to the participant’s records such as the US Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

**What happens to the information collected for research?**

 [If identifiers are removed from your identifiable private information,] the information [may/may not] 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 presented in public talks or written articles, but no information will be presented that identifies you.

[When applicable, include whether assessment or educational relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.]

[For projects taking place in a school, this paragraph must be included:]

Please be aware that under the Protection of Pupils Right Act 20 U.S.C. Section 1232(c)(1)(A), you or your parents have the right to review a copy of the questions asked of or materials that will be used with you or your students. If you would like to do so, you should contact [Principal Investigator] to obtain a copy of the questions or materials.

[Additional note regarding educational data: If your project involves FERPA protected information, you may be required to obtain a written (or electronic) signature.]

**How long will you keep the 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.

**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 personal identified 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, Principle 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** |

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