**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>

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

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.

**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:**

 Briefly list 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 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 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.

**CONSENT TO PARTICIPATE IN RESEARCH**

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

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

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].

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

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 research visit(s) is/are finished, we want to keep in touch with you to follow your [condition] over time. We will [telephone you / ask you to come into the 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 [intervention] you get will be chosen by change, like flipping a coin. Neither you nor the project doctor will choose what 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 research team will know which [intervention] you are getting.

⇒ [For single blinded research, add]You will not be told which [intervention] you are getting, however research team 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 the 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.

**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] 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 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?**

***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 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 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 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. 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 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.

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.

***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 CU IRB Office must be requested.***

***Include the following section if Personal Identified Information (PII) will be accessed or collected about the subject, otherwise delete.***

**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, otherwise delete.***

[Enter text here.]

***If your project involves FERPA protected information, please include the following or submit separate FERPA Consent to Release Student Information, otherwise delete.***

To be in this research project, the principal investigator needs your permission to access, collect and use some of your educational records. If you say no, you cannot be in the project. The only type of information that is to be released under this consent is: [insert which specific records will be requested for use in research activities, e.g., GPA, entrance exam scores, etc.].

***For projects taking place in a school, this paragraph must be included, otherwise delete.***

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 name] to obtain a copy of the questions or materials.

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

One risk of taking part in a research project is that more people will handle your personal 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 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 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 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 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, 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***.

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| --- | --- | --- |
|  |  |  |
| **Subject’s Name** *please print* | **Subject’s Signature** | **Date** **OR Date/Time** |
|  |  |  |
| **Name of Parent Legally Authorized Representative** (if applicable) *please print* | **Signature of Parent or Legally 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** |
| **Rational 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.*

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

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |