*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) where the* ***CU IRB will be serving as the IRB of record for one or more sites*** *engaged in research.*

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

**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.

**CU 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, representing Campbell University and orange type, representing non-Campbell site. **Please maintain the blue/orange colors 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.

* Use simple language. Avoid technical terms.
* Write in a conversational tone, as though you’re speaking to the potential participants.
* Use pronouns (I, we, you) and contractions (we’re, won’t, isn’t). The template default is “we”, you can change this to “I” if you’re doing the research entirely on your own.
* Use short paragraphs.
* Use bullet points, tables, graphs, pictures, diagrams, etc. to more clearly convey the project information.

**Campbell University or <local site>**

**INTRODUCTION TO THE INFORMED CONSENT**

<Project Title>

**LOCAL SITE**

<Site Principal Investigator>

<Name of Local Site>

<Department>

<Local Site Telephone Number>

<Name of Local Site>

<Local Site Address>

<Local Site City, State, Zip Code>

**CAMPBELL UNIVERSITY**

<Principal Investigator>

<Department>

<Telephone Number>

<Campbell University>

<P.O. Box <Number>

<Buies Creek NC 27506>

The first page of this document includes an overview of this project to help the participant decide whether or not to participate. The overview should be a concise and focused presentation of key information. Complete the following box with a very brief explanation in simple language for each line below. You can provide more details later in the document.

**Overview**

**Purpose:** This 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 …]

**[List of visits:**

* <Screening Visit>
* Total Number: \_\_\_\_
* Total Time: \_\_\_\_
* <Baseline Visit/Visit 1or some other descriptor>
* Total Number: \_\_\_\_
* Total Time: \_\_\_\_]

**[Procedures/ Activities 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.]

**Time Commitment:**

* You will be in this research project for about […estimate length of time of subject’s involvement.] Research activities will occur for […estimated length of time.]
* [We would also like to follow you for…estimated length of time of follow-up.]

**Primary risks:** This is a brief list of the most commonly seen side effects or risks associated with the research. [Explain risks here.]

**Benefits:** Monetary reimbursement for participation is not a benefit.

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

**My Other Options:** [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.

**CONSENT TO PARTICIPATE IN RESEARCH**

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

You are being invited to participate in this research because [“you are a student enrolled in…” or “you have been diagnosed with…” or “of your diabetes, you may be eligible for an educational program…”]

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

Under federal regulations, a group of people (called an Institutional Review Board or IRB) is required to review human research projects to make sure appropriate protections are in place for research subjects. The IRB at Campbell University will be reviewing this project for all/some sites involved, which is why Campbell University contact information and the Campbell University Principal Investigator’s name have been included in this consent form.

A total of about [xx] people are expected to participate in this research [nationally / world-wide/ all at / including about xx at].

The lead investigator of the project at [*insert specific institution*] is [Site Principal Investigator name]. A research team works with [Site Principal Investigator name]. You can ask who these people are.

***List any funding source for the project, including departmental or internal funding:***

The [Principal Investigator name and/or [*Institution name*]. Will be paid by the Sponsor, [insert Sponsor name] for conducting this project.

***If a financial conflict of interest, including at the relying site, needs to be explained, state it here.***

[Funding source] is funding this research. [Principal Investigator name] receives financial support from [funding source].

**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. [If you do not agree to join, or if you leave, 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. Take as much time as you need to make your choice.

**Why is this project being done?**

***Describe the purpose of the research. While you may phrase the purpose in a way lay people may understand, do not be evasive about the real purpose.***

The purpose of this project is [to test whether a nutrition program we have developed leads people to eat healthier.]

**How long will I be in the project?**

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

* You will be in this research project for about [estimate length of time of subject’s involvement].
* The principal investigator may stop your participation in the project at any time for any reason without your consent. They will tell you if this happens.

**What will happen if I participate?**

***Describe the project procedures in terms that can be understood by people not in the academic or medical field, tell the participant what to expect using lay language and in clear and simple terms in a narrative form.***

* ***Begin with screening procedures, if any.***
* ***Describe the groups and randomization, if it applies.***
* ***Include duration of each visit or procedure and how recordings will be used, if applicable.***
* ***Explain which procedures are experimental.***

[Enter text here]

***Include any state-specific or institution-specific laws or rules that may apply to this project (i.e., infectious disease reporting, mandatory reporting, etc.)***

[*Insert state/local context or site-specific context applicable to this project.*

*Please note – any local context information for which equivalent language is present in Campbell University’s template language in other areas of the consent form should not be inserted here.*

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

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

***Modify as needed for the project***

You may stop at any time. If you decide to leave the project, please let the research team know.

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

**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 investigator or a member of the research 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 un 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. Rate 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 research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, 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.

**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.

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

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

* This project will not help you, but we hope the information from this project will help us develop a better understanding for [enter topic]…or help us provide better services for [enter topic].
* This project may or may not help you, but we hope the information from this project will help us develop a better understanding for [enter topic]…or help us provide better services for [enter topic].

**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 not costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact, [Site Investigator].
* The costs to you of being in this project are [list as applicable]. If you have questions regarding costs, please contact, [Site Investigator].
* *Include only if harm language module will be included below:* 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.

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

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

* You will be paid [$] after each visit for your time in competing the [research activity / procedure]. To pay you, we need your social security number. [If paid through Campbell University, any payment may be reportable as income on your taxes.
* You will not be paid for participating in this project.

***Include this language if subject’s biospecimen(s) 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 [Site Investigator] will pay you if this happens. You will not receive any payment or commercial rights for products, data, discoveries, or materials gained or produced from your <information / biospecimen(s)>.

***Include only if applicable, otherwise delete***

**What Other Healthcare Choices Do I have?**

You do not have to join this project. You are free to say yes or no.

* Whether or not you join this project, you are free to seek services from this or other agencies.
* Whether or not you join this project, your usual medical services will not change.

***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]

**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.

***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 chance 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 finding 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.

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. The [data/biospecimens/images/etc.] will/will not be reviewed by a physician who normally reads such results. We will provide you with this information so that you may discuss it with your primary care physician.

[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:***

When research [data/biospecimens/images/etc.] is/are collected and analyzed, there is the chance 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).

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 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 [Site Principal Investigator name] at [phone number]. The lead Principal Investigator at Campbell University is [CU Principal Investigator name]. They can be reached 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 [local research subject advocate information] or the IRB Office at 910-893-7780.

***Delete the following section if no identified health information will be collected about the subject.***

***If the relying site wishes to utilize a separate local HIPAA authorization form instead of embedding the HIPAA authorization within the consent form, the following section may be removed, and a copy of the HIPAA authorization form must be included in your submission. If a separate HIPAA authorization is NOT being utilized, the following information must remain in its entirety, and changes to the section are not typically approved.***

**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.

***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.***

The protected health information (PHI) originates from services you will or have received at [name of Campbell University clinic] and [insert locate site(s)].

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>]/[local site], those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the Campbell University rules and/or [local site] are followed.

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

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.

**Delete this paragraph if no one outside of the Campbell University research team will access identified data.**

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/[local site]. 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:

**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.**

 [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/[local site]. 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 information [and/or biospecimens], 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 [Site 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***.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **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** |
| **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.*

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