

**Institutional Review Board (IRB) Resource Guide**

**INFORMED CONSENT**

**\*\*The purpose of the Informed Consent Document is to provide details of your study to potential research participants. While much of the details of your study will be communicated to the IRB reviewers in Form 1, the Informed Consent Document allows the IRB an opportunity to ensure all necessary information is being provided to the potential participant in an easily-understood manner.**

1. Begin by including a title that matches the title listed in Form 1.
2. The Informed Consent Document, as the sample document shows, begins with a brief statement of the research study and the purpose of the Informed Consent process
3. While you will provide more detailed information later in the document, the KEY INFORMATION section asks for a succinct and easily-understood summary of your project and what the participant will be involved with.
4. Provide contact information for the Principal Investigator
5. Provide pertinent information for each of the subsections shown in the template.
6. Upon obtaining IRB approval, be sure to update your Informed Consent Document to list the IRB approval date
7. *OPTIONAL: If conducting a study with multiple sessions or testing visits, please consider adding additional signature lines for the purpose of “reconsent”*

**Informed Consent Form subsections with helpful guidance:**

**Subsection: Title**

* Begin by including a title that matches the title listed in Form 1

**Subsection: KEY INFORMATION**

* Provide information related to:
  + The fact that consent is being sought for research, and participation is voluntary
  + The purpose of your research study, the anticipated duration of your study for the participant, and what the procedures of the study will be
  + Reasonably foreseeable risks of participating in the study
  + Reasonably expected benefits of participating in the study

**Subsection: PROCEDURE TO BE FOLLOWED IN THE STUDY**

* Add a description of the procedures to be followed in your study and include information on the expected duration of study participation
* Be sure this content includes the same procedures that are in form 1.

**Subsection: DISCOMFORTS AND RISKS FROM PARTICIPATING IN THIS STUDY**

* List any and all potential risks or discomforts that may come about as a result of participation in the study
* Example: *“There are no direct benefits to you participating, but you will be contributing to researcher’s knowledge on …….”*

**Subsection: EXPECTED BENEFITS**

* Provide information on any expected benefits of your study
* Example: *“There are no direct benefits to you participating, but you will be contributing to researcher’s knowledge on pressure injury prevention.”*

**Subsection: INCENTIVES AND COMPENSATION FOR PARTICIPATION**

* Detail all incentives and compensation offered for participation in the research study
* Identify how the participant will receive their incentive. If someone will be providing the incentive who is not on the research team describe how that person will have access to the participants and what identifiable information will be share to the person providing the incentive (this is needed when someone is contacting participants to send gift cards as they will have access to the participants email)

**Subsection: CONFIDENTIALITY OF RESULTS**

* Clearly communicate how you plan to maintain confidentiality of results and how you will de identify he data
* Describe how and where you will store and protect the completed questionnaires and logs.
* Example: *“Participant numbers will be used to record your data, and these numbers will be made available only to those researchers directly involved with this study, thereby ensuring strict confidentiality. This consent form will be destroyed after 3 years. The data from your session will only be released to those individuals who are directly involved in the research and only using your participant number.”*

**Subsection: FREEDOM TO WITHDRAW**

* State that participants in your study have the right to withdraw from the study at any point.
* Example: *“You are free to withdraw from the study at any time. You will not be penalized because of withdrawal in any form. Investigators reserve the right to remove any participant from the session without regard to the participant’s consent. Participation in this project will have no impact on your employment (or care, or your grade, or your normal services).”*

**Subsection: CONTACT INFORMATION**

* Provide additional contact information for the PI, members of the research team, and other parties, as necessary