TEMPLATE FOR ADULT CONSENT FORM

Date:

Title. Using all capital letters and bold font, state the title just as it appears on the application.

IRB # (assigned upon approval) **Approval Date:** **Expiration Date:**

Salutation. Dear [role that makes them eligible to participate, such as Dear Nursing Educator:]

Introduction. Introduce yourself and your role (e.g., student investigator and program of study) and invite the prospective participant to take part in the study. For example,

> You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.

Reasons why they are asked to be in this research study. Explain briefly and simply why the prospective participant is eligible. As appropriate, include major inclusion criteria. For example,

> You are being asked to be in this study because you are either an employee or a supervisor who has been working the night shift for at least one year.

Body paragraphs. State the purpose of the study with a brief background to help the potential subject understand why the research is being done. Use objective, unbiased language without reference to the potential participant. For example,

> People who work at night use different strategies for staying awake during their shifts. These methods are likely to be different between employees and supervisors because of their different levels of responsibility. This research is designed (1) to better understand these strategies and (2) to determine whether supervisor strategies could be successfully used by employees.

Description of what will be done. Describe the steps of the study chronologically using simple language and short sentences. For readability and visual appeal, avoid paragraphs more than 7 lines. Include *when* the research will occur, *where* it will occur, *what* will happen, and *how* much time will be needed.

If it is important for them to know in making an informed decision that the study involves randomization, explain that they will be assigned by chance to a study group and explain the study groups. List any other requirements for subjects, such as follow-up interviews or surveys.

Write from the point of view of potential subjects so they have everything they need to make a fully informed decision.

Potential risks. The most serious and common risks should be addressed first, followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress. Stating that there are no known risks for participating in the research study does <u>not</u> preclude describing possible risks as listed in the application.

Protection against risks. If the research requires collection of sensitive information (social, financial, legal, or other) from participants, include a brief description of the precautions you will use to protect that data. If you will share or distribute information from this study to other entities, including study site management, you must disclose that to potential participants for fully informed consent. The following standard language can be used:

> The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law. The information from this study will be presented at Graduate Symposium [add any other entities] and may be published in scientific journals or presented at scientific meetings. However, reasonable steps will be taken to protect your privacy and the confidentiality of your study data, and your identity will be kept strictly confidential.

Potential benefits to subjects. If direct participant benefits can reasonably be anticipated as a result of participation, describe these possible benefits. Using the conditional "may," add that they may not get any direct benefit from being in the research study. On the other hand, if direct benefits to the participant are not anticipated, you state, "You are not expected to get any direct benefit from being in this research study."

Potential benefits to other people. State the possible benefits of the study to society in terms of the advancement of knowledge and/or ultimate possible benefits to those in the prospective participants' position.

Alternatives to being in this research study. In reasonable detail, describe alternatives the potential subject has to being in the study. For example, "Instead of being in this research study, you can choose not to participate."

Cost of participation. State the commitment in time and any financial obligations the participant will incur as a result of participation. If there are no financial obligations, you can state, "There is no cost to you to be in this research study*."*

Compensation for participation. If the subject will receive any monetary or tangible compensation or reimbursement for participating, state the amount of compensation and conditions for payment. If no compensation is provided, you can write, "You will not be paid or compensated for being in this research study."

Participant problem during the study. Your estimation of risk determines what additional information you will include. Clarkson College will not approve studies that pose greater than minimal risk to subjects. For studies classified as minimal risk, you can use the following:

> Your welfare is the major concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

Rights of research participants. Inform potential subjects of the following:

> You have rights as a research participant. These rights have been explained in this consent form and in "The Rights of Research Participants" that you have been given. If

you have any questions concerning your rights, talk to the investigator(s) or contact the Clarkson College Institutional Review Board (IRB) at 402.552.3100.

When a potential subject decides not to participant or when a subject decides to stop participating. You can use the following standard sentences:

> You can decide not to be in this research study, or you can stop being in this research study at any time before, during, or after the research begins. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator(s), Clarkson College, or [name(s) of any other sites or entities].
>
> You will not lose any benefits to which you are entitled. If the research team gets any new information during this research study that may affect whether you would want to continue being in the study, you will be informed promptly.

Informed consent. Tell potential participants that if they choose to participate, they should [do whatever you are asking them to do] and how long participation will take (refer to your *Description of Methodology*). Remind them of the following:

> Participation is strictly voluntary, and your responses or decision not to respond will not affect your relationship with [*Study Site(s)*], Clarkson College**,** or any other entity. Your completion and submission of the [data tool] indicate your fully informed consent to participate.[1] You may withdraw at any time by not completing and submitting the survey (or ending the interview). This study does not cost you in any way, except the time spent completing the [tool or interview].
>
> Please read *The Rights of Research Participants* below. If you have questions about your rights as a research participant, call the Clarkson College IRB Board at 402-552-3100 or email IRB@clarksoncollege.edu. If you have comments, problems**,** or questions about the study, contact the researcher(s), and thank you for considering our invitation to participate.

Documentation of informed consent. You can use the following standard paragraph:

> You are freely making a decision whether to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered, and (4) you have decided to be in the research study. If you have any questions during the study, contact one of the investigators listed below. You will be given a copy of this consent form and "The Rights of Research Participants" to keep. If you are [add legal age] years of age or older and agree with the above, please sign below.

Signature of Participant: _____ Date and Time: _____

Participant's initials. Add a line at the bottom of each page for a participant to initial to show they have read each page.

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[1] Alter the wording for participation in a scheduled live interview.

Then include a statement from the investigator(s):

> My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the participant. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

_____ _____

Signature of Investigator Time and Date

Authorized Study Personnel. Identify all personnel authorized and CITI-certified to document consent as listed in the IRB application. Use the following subheadings: Principal Investigator, Co-Investigator, and Participating Personnel. Include daytime phone numbers and emails for all listed individuals.

Principal Investigator: _____ Phone: _____ Email: _____

Co-Investigator: _____ Phone: _____ Email: _____

Participating Personnel: _____ Phone: _____ Email: _____