# ADULT INFORMED CONSENT DOCUMENT

Revised June 2024

# Q: When should I use THIS template?

# A: When you need to gain and document informed consent from adult study participants during non-exempt human subject research. This form requires a signature or a typed name, so it is not appropriate for anonymous surveys.

# Q: How should I customize or modify this template for my study?

# Fill in the details of your particular study in the spaces presented in [*brackets and italics*] below. Do not leave these sections unchanged in your final document.

# Include all the relevant information that a person would need in order to make the informed decision whether or not to participate in your study.

# It should be written in language and at a reading level that all potential participants will easily understand. Do not use scientific or technical jargon unless it is clearly defined.

# Q: How should I present this document to participants?

# A: You must use only the version of this document approved by the IRB. Allow participants time to read the document carefully and ask questions before signing the form. After they sign, SAVE the signed form in your records. Then, give the participant a copy for their records.

# Please contact the IRB Administrator, Carole Krus (ckrus@jcu.edu, SIH250, 216-397-1527) with any questions about the informed consent process in human subject research.

[**Insert Study Title**]

You are being asked to participate in a research study about [*insert general statement about your study*]. You are selected as a possible participant because [*explain how subject was identified*]. Please read this form and ask any questions before agreeing to be in the research.

## This study is being conducted by *[student or faculty researcher(s)*] at John Carroll University.

**BACKGROUND INFORMATION**

The purpose of this research is [*explain the research question and purpose*].

# PROCEDURES

## If you agree to be a participant in this research, we would ask you to do the following things:

* *[Describe all the procedures to be followed. Include audio taping or videotaping, if applicable.]*
* *[State the duration (subject time commitment) and location of the study.]*

# ELIGIBILITY REQUIREMENTS

* *[Add all eligibility requirements such as “You must be 18 years of age or older to participate.”]*
* *[Include any exclusion criteria, if applicable.]*

# RISKS AND BENEFITS

## This research has the following risks….

* *[Explain any expected risks or discomforts a subject may experience and the likelihood of the risks/discomforts. Risks may be physical, emotional, financial, etc. If there are no known risks/discomforts to participation say* “There are no known risks associated with this research*.*”]
* *[If there is a significant risk or discomfort, the subject should be told under what conditions the researcher will terminate the study.]*
* *[Include all pertinent information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate the research.]*

## The benefits to participation are….

* *[Explain benefits of participation that will be gained by the participants or by others. Note compensation is not a benefit.]*

# COMPENSATION

## You will receive the following compensation for your participation…

* *[Explain the amount of compensation such as college credit, food, gift certificate. If there is no compensation say* “There is no compensation for participation.”]

# ALTERNATIVES

* *[List any alternatives to the study (i.e., subject may choose to do an alternative class assignment for extra credit instead of participating in the research.) If there are no alternatives you can exclude this section.]*

# PRIVACY

* *[List the extent to which confidentiality or anonymity of the data and privacy of the subject will be maintained.]*
* *[State who will have access to the data.]*
* *[State that data may be published or publicly presented and how privacy will be maintained (i.e., no identifying information will be shared, pseudonyms will be used, etc.)]*
* *[Provide one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:]*

“Your personal data, with all identifiers removed, could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.”***or***

“Your personal data, even with all identifiers removed, will not be used or distributed for future research studies.”

* *[If applicable and with respect to confidentiality and/or anonymity, explain how data and/or consent forms will be distributed, collected, returned, and handled (i.e., will consent forms or surveys be sealed by subjects in separate envelopes before they are returned, will consent forms and surveys be collected and stored separately, etc.)]*
* *[If applicable, state how audio/video recordings will be made and used (i.e. transcribed, copied, etc.), who will have access to them, and when they will be erased or destroyed.]*
* *[If applicable for class instructors, state that consent forms will be kept in a sealed envelope and not viewed until grades are posted to address potential coercion.]*
* *[If applicable, state that data will be collected or shared with a third party and explain why this will be done and what steps will be taken to protect the subject’s privacy.]*
* *[If applicable for web-based data collection, inform subjects of the security (i.e. is the web site secure or encrypted, who will collect the data, will the data be collected with or without identifiers such as email or IP addresses.)]*

# VOLUNTARY PARTICIPATION

Your participation is voluntary. There is no penalty if you choose not to participate, and you are free to withdraw at any time.

* *[If applicable, add a statement such as* “There is no loss of benefits if you choose to withdraw” *or state how compensation will be prorated.]*
* *[If applicable, state that a subject may skip any questions they do not feel comfortable answering.]*
* *[If applicable, state that the subject may request the audio/video tape to be turned off at any time.]*

# CONTACTS and QUESTIONS

The researcher(s) conducting this study [*is/are*] [*name(s) of* *Principal Investigator and Co-Investigators, if applicable*]. If you have questions you may contact them at [c*ontact information*].

## This research study has been reviewed and approved by the John Carroll University Institutional Review Board (IRB). If you have questions about the rights and welfare of research participants please contact the John Carroll University Institutional Review Board Administrator at irb@jcu.edu or (216) 397-1527.

**RETURN INSTRUCTIONS**

*[Include any instructions such as how to return the survey or consent forms (i.e. seal the consent form in the self-addressed envelope provided, return the survey to the instructor, etc.]*

# STATEMENT OF CONSENT

## I have read and understand the information above and I willingly give my consent to participate in this research study. I am 18 years of age or older *[If applicable, add any other inclusion or exclusion criteria here.]*

Name (Please Print):

Signature:

Date:

**A COPY OF THIS CONSENT IS BEING PROVIDED FOR YOUR RECORDS**

*[Provide copies for participants, and store signed consent forms for at least three years after the completion of the study.]*