INFORMED CONSENT DOCUMENT

Please use this template to produce an informed consent document to be presented to study participants 18 years and older. This document should present 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 will be easily understood by all potential participants. Do not use scientific or technical jargon unless it is clearly defined. Study participants must be given the opportunity to ask questions before they sign this document.

Please contact the IRB Administrator, Carole Krus (ckrus@jcu.edu, 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 study*]. You are selected as a possible participant because [*explain how subject was identified*]. Please read this form and ask any question before agreeing to be in the research.

This study is being conducted by [*student, if applicable*] 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 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 eligibility requirements such as "You must be 18 years of age or older to participate."*

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 <u>significant</u> 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 presented at a conference (or how it will be publicly presented) and how privacy will be maintained.*
- *Provide one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:*

  (i) A statement that identifiers might be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; ***or***

  (ii) A statement that the subject's information collected as part of the research, even if identifiers are 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 (web based surveys), 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.)*

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. [*Note that a subject cannot withdraw once an "anonymous" survey is submitted; however, a subject may choose not to complete the survey.)*

- *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.*

- *<u>If applicable</u>, 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 [*Responsible 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
- *Add any other 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.

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.]

Revised: November 2019