#

*Note*: Items in red font should be addressed. There should be no red font on the final form you submit to the IRB.

# ***Template for informed consent***

## TITLE OF RESEARCH STUDY

**Subject Informed Consent**

### Introduction and Background Information

### You are invited to participate in a research study. The study is being conducted by Dr. (principal investigator) and (Co-I and/or student’s name). The study is sponsored by (list if the study is sponsored by an outside source) the Department of (name), Bellarmine University. The study will take place at (name of sites where study will be conducted). Approximately (give number) subjects will be invited to participate. Your participation in this study will last for (give time in days, months, years, or hours).

### Purpose

### The purpose of this research study is to (include a brief description of the scientific purpose of the study. This description should be in lay terms, written so subjects reading at a 5th grade level could understand. A brief background should be included.).

### Procedures

In this study, you will be asked to (Include an explanation of any questionnaires, surveys or other instruments the subject will be asked to complete and explain their purpose. Clearly note if there are multiple sessions and how long each session will take. Explain randomization if relevant to your procedures. If a survey or interview is utilized, be sure to note subjects may decline to answer any questions that make them feel uncomfortable or might render them prosecutable.)

### Potential Risks

There are risks associated with (study procedure) which are (Describe any risks that may occur in the study. If there are no foreseeable risks, say “there are no reasonably foreseeable risks”).

### Benefits

The possible benefits of this study include (list any possible benefits for the subject or for humankind- do not overstate the potential value of yours study.). The data collected in this study may not benefit you directly. However, the information learned from this research may be helpful to others in the future.

### Compensation (We recommend that the section on compensation as a “benefit” be separated from the information above). If there is payment to subject to participate, state here. Payment may be in the form of direct dollar remuneration (indicate the precise amount) or course credit or grade compensation (describe). If there is $ payment, indicate that payment will be made on a pro-rated basis should you withdraw from the study. If there is course credit/grade compensation, note that opportunity to earn equal compensation will be given for those who elect not to participate in this project.If there is no compensation, leave this section out.

### Confidentiality

Although absolute confidentiality cannot be guaranteed, confidentiality will be protected to the extent permitted by law. The study sponsor or the Institutional Review Board may inspect your research records. (Choose one of the two following sentences) Should the data collected in this research study be published, your identity will not be revealed. **OR** Your identity as a subject in this research and the information you provide may be released and published. (If there is compensation for study subjects add the next sentence.) Financial personnel may need to be notified of your participation in order to process compensation payment.

### Potential Future Research Statement

**If your research project involves the collection of identifiable private information or identifiable biospecimens, you must include ONE of the following two statements in this section as appropriate:** (i) Identifiers might be removed from the identifiable private information or biospecimens collected for this research and, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent procedures; OR (ii) Your provided identifiable private information or biospecimens collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

### Voluntary Participation

Your participation in this research study is voluntary. You may refuse to participate or withdraw your consent at any time without penalty or losing benefit to which you are otherwise entitled. **(If withdrawal would put the subject at risk, explain the procedure for safe withdrawal).**

### Your Rights as a Research Subject and Contact Persons

If you have any questions about your rights as a research subject, you may call the Institutional Review Board Office at 502.272.8032. You will be given the opportunity to discuss any questions, in confidence, with a member of the Board. This is an independent committee composed of members of the University community and lay members of the community not connected with this institution. The Board has reviewed this study. **(Do not state approved. This section is mandatory for all studies).**

You acknowledge that all your present questions have been answered in language you can understand. If you have any questions about the study, please contact **(Name and phone number of the Principal Investigator, Co-investigators may be added as well).**

### Consent

You have discussed the above information and hereby consent to voluntarily participate in this study. You have been given a copy of this consent form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Subject or Legal Representative Date Signed

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Investigator Date Signed

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Explaining Consent if other than Investigator Date Signed

If the study invoilves minors, a line for the minor to sign and give their Assent may be necessary.

If, due to formatting, any of the signatures are bumped to the last page with no text of the consent, the IRB advises investigators to use the HEADER/FOOTER function and include a study title header on all pages. That allows anyone reviewing or auditing the file to be clear that the signature page actually goes with the

consent. Please remove this note from the consent form before saving your consent document.

DATE WRITTEN/DATE REVISED must be included at the bottom of every page.

This date must change yearly due to renewal of the study and consent.

The date must also change with any amendments.