CONSENT FORM CHECKLIST

- **You are encouraged to use wording modeled on the consent checklist or the Informed Consent Template.**
- **Use Section Headings similar to the checklist.**
- **Do not use type smaller than 11 font size.**
- **The consent form language should be written at a 5th grade level.**
- **PLEASE PUT THE INFORMED CONSENT ON DEPARTMENT LETTERHEAD.**

INTRODUCTION

Pg.___¶ ___Ln.___ 1. State that the subject is invited (not asked) to participate.

Pg.___¶ ___Ln.___ 2. Indicate it is a research study.

Pg.___¶ ___Ln.___ 3. Name the sponsor. If there isn't any sponsorship outside of the University, state the Department or School as the sponsor. Should read … (conducted by {faculty name first} and {Co-I or student's name second} and sponsored by the (Dept of … at Bellarmine University)

Pg.___¶ ___Ln.___ 4. Indicate the place where the study will be conducted, e.g., office, lab, or home.

Pg.___¶ ___Ln.___ 5. Indicate the approximate number of subjects in the study.

Pg.___¶ ___Ln.___ 6. Indicate the expected duration of the subject's participation (days, mo, yrs, etc.)

PURPOSE AND BACKGROUND

Pg.___¶ ___Ln.___ 7. State the purpose of the study in non-technical language. Only a brief background is necessary.

PROCEDURES

Pg.___¶ ___Ln.___ 8. Describe the procedures of the study.

Pg.___¶ ___Ln.___ 9. If the study involves multiple sessions with the subject, estimate the amount of time for each session.

Pg.___¶ ___Ln.___ 10. If the study involves randomization, state this and explain the term; e.g., a process 'like flipping a coin'.

Pg.___¶ ___Ln.___ 11. If the study involves questionnaire or interview procedures, state that the subject is free to decline to answer any particular questions that make him/her uncomfortable or which may render him/her prosecutable under law, or in the methodology, show why such omissions would seriously affect the reliability or validity of the instrument. For studies in which the answers may render the subject prosecutable, include information on the extent to which confidentiality will be maintained (items 30-33) in this section of the consent form.

RISKS

Pg.___¶ ___Ln.___ 12. Describe any reasonably foreseeable risks and/or discomforts to subjects. If questions are to be asked that may be sensitive and produce discomfort (e.g., recollections of past stressful situations) so state this. If some of the questions answered are incriminating, state that there is a risk of prosecution. If there are no reasonably foreseeable risks, so state.

BENEFITS

Pg.____¶ ___Ln.____ 13. Describe any benefits to subjects or to others that may be reasonably expected from the research. If none, then state "The data collected in this study may not benefit you directly. However, the information learned in this research may be helpful to others in the future."

COMPENSATION

Pg.____¶ ___Ln.____ 14. If there is payment for participation, state this and the amount, and

Pg.____¶ ___Ln.____ 15. Indicate that all such payments will be prorated in the even that the subject withdraws before completion of the study.

CONFIDENTIALITY

Pg.____¶ ___Ln.____ 16. Acknowledge that absolute confidentiality cannot be guaranteed. **Note:** Not needed if the subject will be identified. If so, state this in the consent form.

Pg.____¶ ___Ln.____ 17. State that the sponsor and/or the Institutional Review Board may inspect the subject's records. (Financial personnel may need to be notified of your participation to process payments.) Note: If it is determined by the IRB that the study is Exempt, this item is not necessary.

Pg.____¶ ___Ln.____ 18. State that in all other respects the data will be held in confidence to the extent permitted by law. ***Note:** Not necessary if the subjects will be identified. If so, state this in the consent form.

Pg.____¶ ___Ln.____ 19. State that, should the data be published, the subject's identity will not be revealed. **Note:** Not necessary if subject gives consent to be identified. If so, state this in the consent form.

VOLUNTARY PARTICIPATION

Pg.____¶ ___Ln.____ 20. Indicate that participation is voluntary.

Pg.____¶ ___Ln.____ 21 Indicate that the subject may refuse to participate or withdraw their consent without incurring any penalty or losing any benefits to which he/she is otherwise entitled.

RIGHTS AS A RESEARCH SUBJECT

Pg.____¶ ___Ln.____ 22. State this section as written: "If you have any questions about your rights as a research subject, you may call the Institutional Review Board office at 502.272.7963. You will be given the opportunity to discuss any questions about your rights as a research subject, 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.*** ***Note:** This statement may not be necessary if the IRB determines the study is Exempt.

Pg.____¶ ___Ln.____ 23. State that all present questions have been answered in language the subject can understand. ***Note:** This item is about present questions and about the language in which they have been (not will be) answered. The issue is not whether the subjects know that they have a right to have questions answered, but that their current questions have been answered at the time they signed the form.

Pg.____¶ ___Ln.____ 24. Indicate whom to contact (name and phone number for the PI, Co-I's may also be listed) for answers to questions about the research.

ACKNOWLEDGEMENT OF CONSENT AND SIGNATURES

Pg.____¶ ___Ln.____ 25. State that the subject acknowledges having been given a signed copy of the Informed Consent form, or by returning the completed survey, the subject acknowledges their participation.

Pg.____¶ ___Ln.____ 26. Provide lines for the signatures of the parties involved (subject/legal representative, and investigator). Include a separate "date signed" line for each signature line. If the IRB requires, an additional line may be needed for minors to sign. Generally, minors aged seven or above, if able, would sign a consent form written at their level of understanding. Minors 12 and above could sign an line indicating their assent (awareness of his/her role in the study) added to the Parental Informed Consent.

Pg.____¶ ___Ln.____ 27. Provide a line for "Person Explaining Consent if other than the Investigator." Include a "date signed" line.

POTENTIAL CONFLICT OF INTEREST-only applicable for sponsored studies.

Place the following statements in the "Rights as a Research Subject" section.

Pg.____¶ ___Ln.____ 28. This study involves a conflict of interest because the institution and/or the investigator will be compensated for your participation in it.

Pg.____¶ ___Ln.____ 29. You should ask the investigator how the institution and/or she (he) will benefit by your participation in the study.

On all pages _____ **30.** Include the study title as a header and a "DATE WRITTEN" as the footer on all pages.

DO NOT BOLD OR UNDERLINE ANY WORDING IN THE CONSENT EXCEPT FOR HEADINGS.

PLEASE SEND THIS Consent Form CHECKLIST (COMPLETELY FILLED OUT) WITH YOUR SUBMISSION.

If you feel your project does not require subjects to sign an Informed Consent (e.g. retrospective chart study, etc.), or that certain aspects of the Informed Consent are not needed, state the rationale in your submission. The IRB will consider this and decide what is appropriate.