MODEL FORM

TITLE OF RESEARCH STUDY
INFORMED CONSENT FORM (FOR ADULTS)

(Typically used for studies exceeding minimal risk)

Read and address each numbered element of this Model Form in developing an informed consent form for the proposed human research study. PLEASE NUMBER THE CONSENT FORM FOR SUBMISSION TO THE IRB. The numbering may be deleted for data collection. The consent form must be typewritten and written in lay language. The language must be further simplified to meet the needs of a specific population. Please add additional statements when appropriate. Forms must be submitted on and use University of New Orleans letterhead. Note: this form should be printed front to back, or subject will need to initial each page.

1. **Investigator's name, who is title/position, has requested your participation in a research study at this institution.** [Place title of project at top of all pages of consent form.]

2 **The purpose of the research is to...**
[Describe the justification for the research. If appropriate, indicate the number of subjects involved and why the subject is included.]

3. **Your participation will involve...** [Describe the subject's participation and identify those aspects of participation which are experimental. Indicate the expected duration of the subject's participation. If the subjects are students, patients, clients or employees, advise that **participation is voluntary** and that nonparticipation or withdrawal from the study will not affect their grade, treatment, care, employment status, as appropriate.]

4. **There are foreseeable risks or discomforts to you if you agree to participate in the study. The possible risks are... Possible discomforts include...** [***Any*** foreseeable risks ***or*** discomforts are to be explained/described.]

5. **There are alternative procedures available. Alternative procedures include...** [Describe any alternative procedures to be included in language the subject can understand.]

OR

There are no feasible alternative procedures available for this study. If the study includes no intervention, you may delete #5 entirely.

6. **The possible benefits of your participation in the research are...** [Describe the benefits of participants, or lack of benefits, to the individual subject as well as to society.]

OR

Although there may be no direct benefits to you, the possible benefits of your participation in the research are...

7. **The results of the research study may be published but your name or identity will not be revealed. In order to maintain confidentiality of your records, name of investigator will...** [Indicate specifically how the investigator will keep the names of the subjects confidential, the use of subject codes, how this information will be secured, and who will have access to the confidential information. "Confidentiality will be maintained" is not acceptable.]

8. **You will be paid for your participation as follows:** [If payment is to be provided to subject, include amount of payment, method of payment, and schedule for payment including whether payment will be made in increments or in one lump sum.]

OR

You will not be paid for your participation.

9. **Any questions you have concerning the research study or your participation in it, before or after your consent, will be answered by <u>name of individual, university address, and university telephone number</u>.** [This refers to the principal investigator. In the event the investigator is a student, the name of the doctoral or thesis advisor (responsible faculty member) must be included.]

10. **(In case of injury,) If you have questions about my rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, Dr. Roberto Refinetti at 504-280-7481.**[This information must be included in all consent forms. If #4 has indicated "no foreseeable risk, or discomfort"; then first phrase (in parenthesis) should be omitted.]

11. **This form explains the nature, demands, benefits and any risk of the project. By signing this form you agree knowingly to assume any risks involved. Remember, your participation is voluntary. You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given (offered) to you.**

Your signature below indicates that you consent to participate in the above study. (Release statement for videotaping or relinquishing confidentiality must be inserted here if applicable.)

_____	_____	_____
Subject's Signature	Printed Name	Date
_____	_____	_____
Other Signature (if appropriate)	Printed Name	Date

13. **"I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature."**

14. **"These elements of Informed Consent conform to the Assurance given by the University of New Orleans to the Department of Health & Human Services to protect the rights of human subjects."**

15. **"I have provided (offered) the subject/participant a copy of this signed consent document."**

Signature of Investigator_____ Date_____