INSTITUTIONAL REVIEW BOARD
MODEL
INFORMED CONSENT FORM

GENERAL INFORMATION

On the following three pages is a model informed consent form. Because it is based on federal regulations, which must be met, it will be of advantage to you to pattern your consent form on this model.

In what follows, brackets [ ] have been used for two purposes. Where there is a choice of words given, include in your form only the choice that is appropriate; modify wording slightly if necessary. Secondly, brackets are used to give you instructions with regard to what information about your experiment/research you ought to include. Do not repeat instructions in your consent form, but simply put forth in your own words the information that the volunteer needs in order to provide an informed consent.

The Informed Consent Form is a legal document, which must include these three main elements:

a. Explanation to the prospective volunteer of the nature of the research and the procedures involved as these pertain to the volunteer as outlined on page 2.

b. A signature statement indicating that the volunteer has read and understands all of the explanations, and agrees to participate in the research.

c. A signature statement by the investigator that the volunteer exercised full freedom in agreeing to participate in the project.

Although the assent of children over the age of seven years must be obtained, where the volunteer is a minor or under some other legal disability, the volunteer's consent must be given by a legally authorized representative; this is necessary even if the minor (less than eighteen years of age) is willing to participate. In such instances a modified version of this form (b, above – available from IRB) must be used; this must include an indication of the relationship to the volunteer (parent, legal guardian, etc.) and the full address of the representative if different from that of the volunteer. Provision for all this must be included on the form.

Be sure adequate space is provided on the blank lines (signature, address, date, etc.) and between lines so that the writing is fully legible.

The entire complete consent form (not just the signature page) is to be prepared in duplicate for each volunteer involved in the research. One complete form with signatures is to be given to the volunteer, the other complete form with signatures is to be retained by the investigator (or Department) for a period of not less than three years following the official termination of the project.

RESEARCH PROJECT DESCRIPTION

[BRIEF TITLE OF THE RESEARCH PROJECT]

TO : [Full Name of Volunteer] _____

My name is [give full name of principal investigator]. I am a student [faculty member, etc.] in the Department of [name of department; college/school] at the University of Detroit Mercy.

I have asked you to agree to be a volunteer in some research [an experiment, etc.] I plan to conduct. Before I can accept your consent, I want to make known to you the following information pertaining to the project.

1. **Explanation of the Purpose.** [Set forth here a fair explanation of the purpose of the research and the approximate number of volunteers involved in the study. Avoid language and word usage the volunteer in light of age, educational background, etc., is not likely to understand adequately well in order to provide a fully informed consent.]

2. **Explanation of the Procedures.** [Set forth here a fair explanation of the procedures to be followed and their purpose. ***Include identification of any procedures, which are experimental.*** Include a detailed account of what you are asking the volunteer to consent to do. Include the expected duration of the volunteer's participation. Avoid language and word usage the volunteer in light of age, educational background, etc., is not likely to understand adequately well in order to provide a fully informed consent.]

3. **Expected Risks.** [Set forth here a description of any attendant discomforts and risks reasonably to be expected. If there are none, state: There are no attendant discomforts or risks reasonably to be expected. If the research includes particular treatment or procedures that may involve risks to the volunteer(s) (or to an embryo or fetus, if the subject is or may become pregnant) which is currently unforeseeable, so state this.]

4. **Expected Benefits.** [Set forth here a description of any benefits, which reasonably might be expected to accrue to the volunteer or to others. If there are none, state: Other than participating in an important research project, there are no particular benefits, which reasonably might be expected to accrue to you or to others.]

5. **Appropriate Alterative Procedures.** [Set forth here a disclosure of any alternative procedures that might somehow be advantageous to the volunteer were they carried out in place of the intended research procedure planned here. If there is an alternative procedure that might somehow be advantageous to the volunteer, indicate clearly why the proposed procedure is being used. ***NOTE: If project does not involve a treatment or therapy then this section may be deleted.***]

6. **Confidentiality.** [Describe how confidentiality will be maintained. If complete confidentiality cannot be maintained, describe any limits to confidentiality. Include the following statement: The confidentiality of the records will be maintained unless the law requires disclosure. Confidentiality of records will be maintained by _____ .Limits to confidentiality include _____ . NOTE: In certain cases the FDA may inspect the records, the sponsor may inspect the records, and/or the IRB may inspect the records.]

RESEARCH PROJECT DESCRIPTION (CONTINUED)

7. **Offer To Answer Questions.** [Text to include: I hereby offer to answer any questions you might wish to ask concerning the procedures used in this research at this time. Furthermore, I may be reached during the hours of ### AM until ### PM at ###-###-#### or by e-mail @ ######@udmercy.edu. You should also identify another individual who could be contacted regarding the research project ***(provide name, telephone number, e-mail address and street address).*** If you have questions concerning your rights as a volunteer, you may contact Dr. Frank E. Pink, Chair, UDM Institutional Review Board, (313) 494-6782 or {pinkfe@udmercy.edu}.]

8. **Freedom To Withdraw Consent.** If you consent to be a volunteer in this research project [experiment, etc.], you are nonetheless free to withdraw your consent and discontinue participation at any time without prejudice to you. [This will include students participating in research projects within a course and no penalty to a course grade or class standing will precipitate from withdrawal as a subject.] You should also understand that the investigator has the right to withdraw you from the research project at any time. [Indicate anticipated circumstances under which the volunteer's participation may be terminated without regard to the volunteer's consent. An example would be the failure of the volunteer to follow instructions given to them by the investigator.]

9. **Compensation.** [If applicable, specify the time period over which payments will be made to the subjects. If the volunteers are to be paid or compensated, specify dollar amount and address the matter of prorating if the volunteer withdraws or if the investigator terminates the study.]

10. **Availability of Compensation and Medical Treatment for Injury.** [For biomedical or behavioral research, which might result in injury or trauma **of any kind,** set forth an explanation regarding whether compensation and medical treatment (provide prearranged location) are available if such injury or trauma should occur. If compensation and medical treatment are available, indicate of what this consists and/or where further information may be obtained (provide the name, telephone number and address of the individual to contact regarding this). If compensation and medical treatment **are not** available, include the following statement:
You [i.e., research subject] understand that if you are injured, no form of compensation is available. Medical treatment may be provided at your own expense or at the expense of your health care insurer (i.e. Medicare, Medicaid, BC/B.S., etc.) which may or may not provide coverage. If you have questions, you should contact your insurer. ***NOTE: If there is no risk of injury or trauma, you may omit this entire paragraph.***]

11. **Additional Costs.** [If there are any additional costs to the volunteer that may result from participation in the research, outline them fully. When a research study includes randomization with several treatment plans involved, the consent form must indicate whether one plan may be more costly than another plan in the same research study.]

12. **Significant New Findings.** [A statement should be included that indicates that if any significant new findings are developed during the course of this research which may relate to the volunteer's willingness to continue participation, such new findings will be provided to the volunteer.]

13. **Future Data Use.** Occasionally, the same or another researcher will request the permission to review or use previously gathered data from a completed research project for a different project. If confidentiality of the data is protected and if a human subjects protection committee has approved the study, would you be willing to give your permission to the release of your data collected from your participation in the current study without prior notification?

_____ Yes, I give my permission for the future use of data obtained in this study contingent on the preceding conditions.
initials

_____ No, I do not give my permission for the future use of data from this study.
initials

(Page 2 plus page 3 constitute the informed consent and should be kept together. Your word processor should be set up so that the information contained on the next page, page 4, appears on a single sheet of paper.)

ACKNOWLEDGMENT AND CONSENT

I, _____ of _____ hereby state:
(Prospective Volunteer's Full Name) (Street address, City, State, Zip Code)

1. I have read all of the statements above pertaining to the research project entitled [brief title of research project] and I understand them.

2. I have been given the opportunity to ask any questions I wish concerning this research project [experiment, etc],and any questions I have asked have been answered to my satisfaction.

3. I understand a full copy, with signatures, of this document will be provided to me.

4. I hereby consent to be a volunteer in this research project [experiment].

_____ _____
Full Signature of Prospective Volunteer Date

As the investigator in the research project entitled [brief title of research project], I hereby state to the best of my knowledge and belief that all of the statements made in the above consent form are true and that in consenting the prospective volunteer exercised free power of choice without undue inducement or any element of force, fraud, deceit, duress, or any other form of constraint or coercion. In addition to the participation by the volunteer being voluntary, the volunteer has been advised that he or she may discontinue participation at any time without penalty or loss of benefits to which the volunteer is entitled.

_____ _____
Full Signature of Investigator Date

FINAL NOTE: ***The completed Informed Consent Form to be used must be submitted in its intended [not draft] form at the time the proposal is submitted to the Institutional Review Board for its approval.***