# Informed Consent Form Guidelines

Informed consent is an essential part of the design for every research project involving human subjects. Researchers who involve human subjects in their research have both an ethical and legal obligation to secure the informed consent of the potential research subjects before starting their research. These guidelines are intended to assist researchers in complying with the requirements of informed consent for research involving human subjects.

## General Elements of Informed Consent

The basic elements of effective informed consent are:

A. The full disclosure of the nature of the research, with any risks and benefits, and a description of what the subjects will experience;
B. adequate information for the potential subjects to make an informed choice about participating in the research;
C. disclosure of efforts to ensure privacy and confidentiality; and
D. a guarantee of the subject's voluntary choice to participate.

## Specific Elements of an Informed Consent Document

In order to assure that all of these general elements are included, an appropriate informed consent document should include the following written in a language easy for potential subjects to understand:

A. A general description of the study and its purpose or goal.
B. A description of the procedures and measures or observations involved in the study (tell them what they will experience).
C. A statement indicating how much time their participation in the study is expected to take.
D. A description of any benefits which may be reasonably expected for both the potential research subject and for society. If there is no direct benefit for subjects, you should say so.
E. A description of any foreseeable risks or discomforts to the potential research subject. This section should include information from your IRB application regarding possible stress or risks for the research subjects, information regarding personal or sensitive questions, and disclosure, if any,

of the materials to be presented might be considered offensive, threatening, or degrading.

F. An explanation as to what medical and/or mental health care services are available and contact information (the location, and phone number of the MCC Counseling Services) in cases where research involves more than minimal risk to participants.
G. Phone and email contact information for questions or concerns about the research (for each Principal Investigator and faculty mentor).
H. MCC IRB contact information for questions about research participation.
I. A description of how the confidentiality of records identifying the subject will be maintained. This section should include information from your IRB application. We strongly urge that, where possible, data be stored on campus in a secure office file. Your faculty mentor should be able to assist you with this.
   You must specify the location of all documents related to the study and the person responsible for them in case these records need inspection. (Federal guidelines require that signed consent forms be kept at least 3 years following the end of the study.
   You can contact the IRB to discuss storage issues. Completely de-identified data records may be kept as long as needed.
J. A statement that participation in the research is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is entitled, and that the subject has the option to discontinue participation at any time without penalty or loss of benefits.

## Informed Consent Modifications & Waivers

In special situations, evaluated on a case-by-case basis, the MCC IRB may approve a consent which modifies or waives the requirement to obtain written informed consent under one or more the following conditions:

A. The research cannot practicably be carried out without the waiver; (e.g., research that must, due to its design, mislead/deceive research subjects).
B. It is research that involves no more than minimal risk to the research subjects.
C. Subsequent to the research, the research subjects will be provided a statement (information sheet) containing the basic elements of the consent form which describe the research project.