

Human Subjects Research Project Consent Form Checklist

Basic Elements of Informed Consent

Informed consent document must meet all of the requirements detailed in CFR Title 21, Part 50 as well as Monroe Community College's IRB local requirements detailed below.

N/A	Yes	No	Requirements
			The first page of the consent form must be printed on Monroe Community College letterhead of the principal investigator's department.
			The local number of participants anticipated to be enrolled in the study must be listed in consent form.
			The informed consent document must be written at an educational level that is reasonably expected to be understood by the participant ~ 8 th grade.
			A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and the identification of any procedures which are experimental.
			Conflict of Interest Statement – Investigator should state whether he/she is receiving payment for conducting this research.
			A description of any reasonably foreseeable risks or discomforts to the participant.
			A description of any benefits to the participant or to others which may reasonably be expected from the research.
			Confidentiality of Records.
			For research involving more than minimal risk, an explanation as to whether any treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.
			An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of a research-related injury to the participant.

Contact Persons

The consent form must address three (3) areas for participant's questions namely: questions about the research itself, questions about research related injury and questions about the participant's rights. (See the [Institutional Review Board \(IRB\) Policy and Procedures](#)¹ section, "Informed Consent," for examples.)

N/A	Yes	No	Areas to Address
			<p>A statement that participation is voluntary, that refusal to participate will involve no penalty to the participant and that the participant may discontinue participation at any time without penalty.</p> <p>The following formatting requirements for consent forms must be met:</p> <ul style="list-style-type: none">(a) except for the first page, each page of the consent form must contain a header that includes the title (complete or abbreviated) of the study; and;(b) each page of the document must include a "page of pages" number style and version date in the footer. <p>Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the subject's consent. A statement that the investigator, Monroe Community College or Monroe Community College IRB have the right to terminate the protocol.</p> <p>Any additional costs to the participant that may result from participation in the research.</p> <p>A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the participant.</p>

Signature Page Requirements

Monroe Community College's Institutional Review Board requires that a consent form provide a place for the printed name and signature of the person obtaining consent, the participant, and a witness (if the research is greater than minimal risk).

The requirement of a witness is not required by federal regulations; however, Monroe Community College's Institutional Review Board requires this signature for all research with greater than minimal risk to study participants. The intent of the witness is to acknowledge that the participant is giving their consent freely and without reservation, the witness does not need to be present for the entire informed consent process. The witness must be an individual not directly involved in the conduct of the study.

Please refer to Appendix in the [IRB Policy and Procedures](#)¹ for a sample consent form.

¹ Institutional Review Board Policy and Procedure url:
<https://www.monroecc.edu/fileadmin/SiteFiles/GeneralContent/depts/grants/documents/MCC-IRB-Policy-and-Procedures.pdf>