**Note:** Researchers, these three pages provide information about how to create a consent form for participants to sign prior to participation in your study. This model is provided using the *basic elements* as described in 45 CFR 16.116 (b) of the “Revised Common Rule”. Your consent form should be constructed to meet the needs of your study. For *additional elements of informed consent*, see 45 CFR 46.116 (c). For *elements of broad consent*, see 45 CFR 46.116 (d).

# CONSENT FORM

(Please put on NU Departmental Letterhead)

You are invited to participate in a study of (STATE WHAT IS BEING STUDIED). I/we hope to learn (STATE WHAT THE STUDY IS DESIGNED TO DISCOVER OR ESTABLISH). You were selected as a possible participant in this study because (STATE WHY AND HOW SUBJECT WAS SELECTED).

If you decide to participate, you will (DESCRIBE THE PROCEDURES TO BE FOLLOWED, INCLUDING THEIR PURPOSES, HOW LONG THEY WILL TAKE, AND THEIR FREQUENCY.)

(DESCRIBE ANY RISKS, DISCOMFORTS AND INCONVENIENCES THAT MAY REASONABLY BE EXPECTED, AND ANY BENEFITS TO SUBJECTS OR SOCIETY THAT MAY REASONABLY BE EXPECTED.)

(DISCLOSE APPROPRIATE ALTERNATIVE PROCEDURES OF COURSES OF TREATMENT, IF ANY, THAT MIGHT BE ADVANTAGEOUS TO THE SUBJECT.)

Any information obtained in this study in which you can be identified will remain confidential and will be disclosed only with your permission. (IF YOU WILL BE RELEASING INFORMATION TO ANYONE FOR ANY REASON, YOU MUST STATE THE PERSONS OR AGENCIES TO WHOM THE INFORMATION WILL BE GIVEN, THE NATURE OF THE INFORMATION TO BE GIVEN, AND THE PURPOSE OF THE DISCLOSURE.)

(DESCRIBE ANY COMPENSATION OR COSTS RELATED TO PARTICIPATION IN THE STUDY.)\*

Participation in this study is entirely voluntary. Your decision whether or not to participate will not affect your future relations with (INSTITUTION OR AGENCY). If you decide to participate, you may withdraw from the study at any time without affecting your status (AS A PATIENT, STUDENT, ETC.).

If you have any questions about this research, please ask me. If you have additional questions during the study, I will be glad to answer them. You can contact me at: (NAME, ADDRESS AND PHONE).\*\*

You will be offered (given) a copy of this consent form to keep.

You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above and have voluntarily decided to participate.

Signature of Subject Date

Signature of Parent or Legal Guardian Date

(omit for subjects consenting for themselves)

Signature of Investigator Date

\*For research posing more than minimal risk, and/or involving physical activity, see the next page.

 If participation of human subjects poses more than minimal risk, and/or involves physical activity, you must include the following paragraph:

 I have been informed and I understand that Newman University does not provide medical treatment or other forms of reimbursement to persons injured as a result of or in connection with participation in research activities conducted by Newman University, its faculty, or its students. If I believe that I have been injured as a result of participating in the research covered by this consent form, I should contact the Office of Academic Affairs, Newman University.

 \*\* If you are collecting data by means of a mail-out questionnaire, you may substitute the following format from paragraph 8 through the end of the document (see \*\* previous page):

 You are under no obligation to participate in this study. Your completing and returning this questionnaire will be taken as evidence of your willingness to participate and your consent to have the information used for purposes of this study.

 You may keep this cover letter and explanation about the nature of your participation in this study and the handling of the information you supply.

Sincerely,

Name of Investigator

NOTE: The principal investigator must sign this form.