

Daemen College
Human Subjects Research Review Committee
(Sample) Informed Consent

This template is provided for the researcher's guidance in developing an informed consent form. Modifications can and should be made as needed in light of your specific project, but all required parts must be included. See notes on medical research, compensation, letters from other institutions, and child assent forms on the next pages. Consent forms must make it clear that participation is the individual's decision. Therefore, do not start the form with "Dear Participant." **Before submitting your informed consent form, use these instructions as a checklist to be sure have included everything required.**

Title of Research Project:

Description of the Research Project:

[use language a layperson can understand]

Description of Participants' Role:

What will the participant be asked to perform?

How much time will be required of the participant?

Are there any perceived or anticipated risks to the participant? If so, how will subjects be assisted or referred for assistance?

Are there any benefits to the participant? Are there potential benefits to society?

Researcher(s)

This research project is being conducted by:

Name of researcher(s)

Dept. Address of researcher(s) Dept. Telephone number, e-mail address (optional)

Name of researcher(s)

Name of Faculty research supervisor (if applicable), Department phone number, e mail address.

Confidentiality:

All information will be published in group form and there will be no publication that could link your participation with the data. Confidentiality of each participant will be maintained. Any identifying information, such as this consent form, will be stored in a secure location separate from other data.

Consent to Participate:

I agree to participate in this study. I have been informed of the nature of the study and what is expected of me. I am over the age of 18 years. The researcher(s) have explained the research and answered questions to my satisfaction. I understand that I can withdraw from this research project at any time with no penalty. I will receive a copy of this form with the researcher's signature. In the event of any later concerns about this project, I will notify the researcher. Should I have any questions at a later time, I can contact the faculty research project Advisor, (Name, phone number.)

Participant's Signature

Date

Researcher's signature

Date

Additional information for consent forms:

1. The consent form **MUST** be in jargon-free language appropriate to the comprehension level of intended participants. (For studies of the general public, an eighth grade reading level is suggested.) Any acronyms must be spelled out and explained.

2. For studies in **health care settings**, the consent form must list contraindications to participation, if any, and must include participants' signed statements that they do not have these conditions. (Avoid the use of the term "contraindications", or define it.)

3. If any **compensation** is offered to participants, such as course credit, cash or gifts, it should be explained in the consent form, and should be appropriate for the effort and time involved in participation. Compensation should not be at a level that puts undue pressure on potential participants, and it should be made clear that compensation is not forfeited if the person decides to discontinue participation. For studies involving child participants, it is especially important that any gifts for participation be inexpensive items that the child could receive or earn some other way. Prizes such as field trips are considered coercive. Parental consent forms should clearly state that the parent's decision to participate or not will not affect the child's standing in class (grades, for example.)

4. For studies in schools and clinical settings, the consent form must state that the decision to participate or not will not affect the person's care (in clinical research) or the student's evaluation by a teacher. This is especially important if a teacher is conducting research with his or her students or a clinician is studying her or his patients.

5. Child assent forms:

Research involving persons less than 18 years of age must have signed **informed consent forms from a parent or guardian** for each child participant. Studies that meet the exempt criteria (see "What category applies to my research project") do not require parental permission, although researchers may choose to inform parents and gain their approval for exempt studies. In addition to parental/guardian informed consent, researchers should communicate to children that they have a choice about participating, and should obtain **assent** from children who are developmentally able to express their agreement to participate. Child assent forms must be in age-appropriate language. The next page has two sample child assent forms.

5. The Committee will review the consent and assent forms. Do not send signed consent/assent forms to the committee. Keep the forms in a separate location from your other data, and dispose of them by shredding when the study is completed.

6. If your research is conducted at a school, health care facility, or other institution other than Daemen College, you must obtain a permission letter from an administrator of the other institution. These permission letters are not consent forms. They must be on institutional letterhead and must be signed by the administrator and submitted with the hard copy of the application. The letters must include the researcher's name and include the topic or title of the research project. If the research is exempt, because it involves the study of on-going curriculum or unobtrusive observation of classroom behavior, principals' permission letters are

not required; however, the committee advises student researchers to inform principals that they are doing research in the classroom and to show them the Certificates of Exemption. See introductory pages of this web site for instructions in working with other institutions that have their own Institutional Review Boards.

Sample assent form for young children (Grades 1 to 3)

I am Miss Smith. I am a teacher, and I go to school, too, to learn more about being a teacher. For my homework, I am trying to find out what kinds of books girls and boys like. Your mom or dad has said it's ok for me to ask you about books if it's ok with you. If you would like to talk with me about books. Please circle "Yes". If you don't want to do this, circle "No." Either way is ok.

YES

NO

(Or use a smiley face and un-smiley face for a child to circle.)

Print your name here _____

Researcher's name

Date

Sample assent form for a child in middle grades:

I am Miss Smith. I am a student at Daemen College. For one of my classes I am trying to learn more about what boys and girls your age think about friendship. Your mom or dad has said it's ok for me to ask you questions about this, if it is also ok with you. You do not have to answer any of my questions at all, or if you can answer some of them and then decide not to answer others. It is your decision. I will keep what you said private, and anything I write or tell others will not include your name. If you would like to talk with me about friendship, please write your name on the line below.

I agree to talk with Miss Smith about friendship. I understand that it is my choice and I don't have to answer any questions if I don't want to. I understand that she will not use my name when she writes about what I say.

Name

Researcher's Name

Date