

NAZARETH COLLEGE
Human Subjects Research Committee
October 7, 2008

INSTRUCTIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS

Contact Information

Human Subjects Research Committee Website
<http://www.naz.edu/dept/fec/fec2.cfm>

Path:

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Human Subjects Research Committee

Policies and Procedures Governing Human Subjects Research

(October 1, 2008)

Nazareth College of Rochester (the College) values and encourages research involving human subjects and strives to provide opportunities for faculty, staff, and students to engage in this activity. In doing so, the College accepts the legal and ethical responsibilities for safeguarding the rights and welfare of human subjects involved in this research and operates in compliance with the Federal Wide Assurance required for federal funding of research.

The College requires that all research projects that use human subjects be approved and periodically reviewed by the Human Subjects Research Committee (HSRC). The HSRC operates under Section 474(a) of the Public Health Service Act (P.L. 93-348) as implemented by Department of Health and Human Services regulation Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) which details procedures to safeguard human subjects in research.

As defined in CFR Title 45, Part 46, "research" is a "systematic investigation designed to develop or contribute to generalizable knowledge," and a "human subject" is "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." Since class work assignments are usually not intended to or likely to lead to generalizable results, the Human Subjects Research Committee does not normally include these projects under its operational definition of research. However, if the intent of a project is to conduct research (e.g. honors or master's thesis) vs learning about conducting research, the project should be submitted to the HSRC for review. If a project involves in any way the use of human subjects it must be conducted so as to safeguard human subjects in research, including consideration of risks and use of informed consent. See document on student research.

The HSRC functions as the Institutional Review Board (IRB) at the College regardless of the source of funding. The HSRC shall be composed of at least five members pursuant to section 107 of 45 C.F.R. 46. Members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The HSRC shall be sufficiently qualified through the experience and

expertise of its members, and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes and religious beliefs. If research involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or persons with disabilities, consideration shall be given to the special appointment of one or more individuals who are knowledgeable about and experienced in working with these subjects. The members of the HSRC are full-time faculty members elected by the faculty except for one member who is a community representative (someone not employed by the College) appointed by the Committee. The Chair of the HSRC shall be one of the faculty members of the Committee. Members will serve a three-year term and may be re-elected for one additional three-year term.

These policies and procedures apply to all research which is either (a) conducted on the premises of the College; or (b) funded through the College; or (c) conducted by faculty, staff, or students of the College who are acting in connection with their responsibilities or relationships to the College or who intend to use the name of the College in any report of the activity; or (d) conducted through the use of the College's records.

The Application Process

1. Before submitting an application for approval, a researcher must demonstrate his or her awareness of issues involving protection of human subjects by completing a set of training modules available online at www.citiprogram.org (see Training Module Instructions). A certificate of completion provided by the CITI website should be sent to the HSRC as part of the application procedure.
2. If, in consultation with the Chair of the Human Subjects Research Committee, a researcher deems that the proposed research entails survey or program evaluation procedures that qualify as *Risk Free* and thus exempt from review (see Category I below) he/she should submit the Notice of Exempt Research Form to HSRC@naz.edu. The Chair will review this information and verify that the research is exempt from review. If the Chair questions this determination, the researcher will be asked to submit a full application to the HSRC for review.
3. For all research other than those projects approved as exempt, a complete Application for Approval of Research Involving Human Subjects should be submitted **electronically** to HSRC@naz.edu. A copy of the Application can be obtained from the HSRC website (<http://www.naz.edu/dept/fec/fec2.cfm>). Click on "Read Only" to open the form.

Send proposals as Word documents using the following naming convention:

"**NAME.HSRC_Proposal.doc**" Use the PI's last name. When necessary, a letter to a prospective funding agency may be issued stating that the proposed research protocol is under review.

4. The HSRC accepts applications using a rolling submission process. Proposals that are complete and conform to application guidelines will be reviewed within one month of submission with two exceptions:
 - applications submitted after November 15 will have a review deadline of February 1
 - applications submitted after May 1 will have a review deadline of August 25

The HSRC chair will inform an applicant **within one month** of the submission date regarding the status of the proposal (with submission date exceptions noted above and risk exceptions noted below in 1b & 1c). The HSRC review schedule is meant to accommodate the needs and time constraints of Nazareth faculty and students as well as the members of the HSRC.

The applicant should be mindful of the HSRC's review schedule as he or she is considering the length of

time needed to complete the research. Faculty and students who may need to receive HSRC approval for their research as stipulated by granting agencies (e.g., the NSF or the NIMH) should be especially attentive of the HSRC review schedule.

The Review Process

1. The research project is given one of three designations: Category 1 (Risk Free), Category II (Expedited), and Category III (Risk to subjects). The HSRC Chair, in consultation with other members when necessary, reviews the application to determine the appropriate designation
 - a. Category I Research is usually the case for anonymous, mailed surveys on innocuous topics, or anonymous, noninteractive observation of public behavior (e.g., shoppers at a mall). Some typical examples include:
 - 1) research conducted as part of academic coursework involving instructional strategies, techniques, curricula, or classroom management methods;
 - 2) research involving the use of educational tests;
 - 3) research involving survey procedures;
 - 4) research involving observation of public behavior; or
 - 5) research involving the collection of existing data, documents, or records.

Each exemption specifies that no human subjects may (1) be identified directly or through identifiers linked to the subjects; (2) be identified in such a way that subjects could be reasonably placed at risk of criminal or civil liability or incur damage to their financial standing or employability; or (3) be identified in such a way which deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

- b. Category II Research is research carrying minimal risk to the subjects but which does not qualify as Category I research. Category II research includes methods such as interviews or self-report measures or any data collected either one-on-one or in groups in which there is no psychological intervention or deception. Category II proposals require the use of written informed consent forms.

Category II Research qualifies for expedited review. In this situation, an application will be reviewed by two members of the HSRC. If these reviewers deem that the risk may exceed minimal, the application will be reviewed by the entire committee. This may extend the review process beyond a month.

- c. Category III Research is research that involves risk to subjects. Category III research is usually applied to studies involving invasive measurements (such as blood draws), interventions (such as those involving exercise and physical exertion by volunteers), asking about sensitive topics (e.g., sexuality, drug use), experiments involving deception, or use of "special" populations such as minors or prisoners. Category III proposals require the use of written informed consent forms. Proposals given this designation may require a review by the entire HSRC. This may extend the review process beyond a month.
2. After reviewing an application, the HSRC chair will notify the principle investigator of one of five decisions: (a) approval; (b) approval with stipulations; (c) deferral of judgment pending further consideration; (d) change in status to full review; or (e) disapproval. If there are stipulations, they will be specified in writing to the Principal Investigator and must be addressed before the project can be approved.

- a. If approved, the project may proceed as described in the application.
 - b. The designation “Approval with stipulations” means that the HSRC approves the project on the condition that the investigator agrees to specific minor changes. The HSRC Chair communicates this finding to the Investigator and requests that the HSRC receives an appropriately revised application within three weeks. These revisions must be reviewed and approved before the research proceeds.
 - c. The designation “Deferral of Judgment Pending Further Consideration” is used on occasions when the application is incomplete or the HSRC requires further information from the Principal Investigator before ruling on the application.
 - d. The designation “Change in status to Full review” is used when the HSRC chair thinks the proposal should be disapproved or reviewed further. In these cases, a proposal is treated as Full Review Research and the Chair then convenes the HSRC. Note: Full Review research is not necessarily Category III research.
 - e. The designation “Disapproval” means that research may not proceed. The HSRC Chair communicates this finding and the HSRC’s rationale to the Principal Investigator.
3. In the case of Full-Review, either the HSRC or the Principal Investigator can request that the Principal Investigator be present at the part of the meeting of the HSRC when a specific project is considered.
 4. As outlined above, the HSRC chair will inform an applicant within one month after the submission date as the status of his or her proposal. At this time, the Chair will make it clear to the applicant (1) the designation of the proposal (i.e., Category I, Category II, or Category III); (2) whether or not the project is approved; and (3) any stipulations that must be addressed before the proposal is approved. In addition, if the proposal requires a full review, the Chair will clearly outline to the applicant the HSRC’s rationale for convening a full review.
 5. If required, a letter describing the decision of the HSRC will be addressed to the funding agency. Normally, the Principal Investigator will forward the letter to the agency.

Responsibility of the Researcher

Some research involving human subjects must be sponsored by an approved investigator. Investigators whose appointments carry the approved rank codes do not require sponsorship. See the end of this section for a list of approved rank codes. All other investigators, including students, research associates, postdoctoral fellows, non-salaried clinical rank appointees, non-tenure track faculty and librarians, and part-time appointees must be sponsored by one or more full-time Nazareth faculty, librarian, salaried clinical rank, or research rank appointee whose primary appointment carries one of the below-listed ranks.

Sponsorship is more than simply a signature, and carries two responsibilities: (1) assistance in preparing the application for Human Subjects Research Committee approval, and (2) supervision of the research project. While the Committee is able to offer assistance in how to complete the HSRC applications, it cannot take the place of the sponsor.

When a student is working on a project that already has HSRC approval and that student will use some of that data to fulfill a course or degree requirement--such as honor's thesis, first-year project, or master's degree--the original principal investigator must submit an amendment to the HSRC requesting the student to

be added as a co-investigator on his/her project for the stated purpose. Any student working in the same capacity but who wishes to use the data for his/her dissertation must submit a separate application to the HSRC describing the project and the data to be used. In all other situations, student-initiated research must be submitted as an independent project, NOT as an amendment to an already approved protocol. All student projects must be sponsored by one or more full-time Nazareth faculty, librarian, salaried clinical rank, or research rank appointee. If the sponsor's appointment is at another campus, the review must take place on that campus.

Full-time persons with the following ranks are approved to submit, or sponsor, an application to use human subjects in a research project:

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| Professor | Emeritus | Dean |
| Associate Professor | President | Associate Dean |
| Assistant Professor | Vice President | Assistant Dean |
| Clinical Professor | Assistant Vice President | Chairperson |
| Clinical Associate Professor | Associate Vice President | Director |
| Clinical Assistant Professor | Chancellor | Librarian |

About Informed Consent

In addition to concerning itself with risk, the HSRC must consider the subject's consent to participate in the research project. An underlying ethical principle of the Federal regulations is that human subjects enter into research voluntarily and with adequate information. (See "*Ethical Principles and Guidelines for the Protection of Human Subjects of Research*," (1979), known as *The Belmont Report*. <<http://ohsr.od.nih.gov/guidelines/belmont.html>>) Thus, consent must be informed and voluntarily given. A subject's consent is "informed" if he/she has a reasonable comprehension of that to which he/she is consenting. The investigator must use language appropriate to the subject's ability to comprehend. Generally, the consent form should be written at the 7th grade reading level. Nondisclosure of information to subjects must not be used simply to assure their participation in the research. It is desirable, but not mandatory, that the investigator, rather than an assistant, obtain the consent.

To ensure that subjects' consent is voluntary, the HSRC considers whether any undue pressures will be brought to bear on potential subjects. Such pressure may be subtle as, for example, when a teacher asks his or her own students to become subjects of his or her research. Excessive compensation or no payment for withdrawals is viewed by the HSRC as pressure.

In order to obtain informed consent the investigator must provide a statement that includes the information listed on the Informed Consent Statement Checklist. A checklist for the informed consent statement is included below in order to assist investigators in the preparation of their consent form. This checklist reflects both requirements of the Federal regulations and customary language adopted by the HSRC. Use of the checklist will facilitate HSRC review. Each participant shall sign two copies of the Informed Consent form. One copy will be filed by the PI and the other retained by the participant.

Who is to give consent? Any legally competent adult can give consent; but said adult cannot give valid consent if he/she is under the influence of alcohol or drugs, or if the consent is obtained under duress. This latter point is important in academic circumstances since students are often asked to volunteer as subjects. If possible, investigators should not use their current students. If current students must be used, it must be made clear to the subjects that the decision to participate will have no effect upon their grades.

Investigators should be aware that the HSRC will not approve a study involving a researcher's current students even if no adequate alternative design is available, unless the HSRC is satisfied that voluntary consent can be obtained. For guidelines regarding the inclusion of the investigator's own students in research contact the HSRC.

The consent process for studies conducted in foreign countries, or with illiterate populations, may be altered so that consent may be given orally and documented on tape. Such tapes must be treated in the same manner as paper consent forms. Any other alteration to the consent process must be reviewed by the full committee.

Research With Minors

Minors require special consideration. Persons aged 18 and older may consent to participating in research and parental permission is not required. For subjects aged 17 and under, however, the consent of at least one parent or guardian is required. If a child is age 7 or older, the aims and general nature of the project must be described in language the child can comprehend, and the child's assent must be obtained. Children under age 7 need not be asked to assent; parental or guardian consent is sufficient. If biomedical research on infants is planned, the drugs or procedures must first have been tried on animals, adults, and older children. In certain cases where there is no risk and where it would be unreasonable to require parental permission, the HSRC may waive the requirement. Research on minors that involves more than minimal risk will be approved only if it is (i) of direct benefit to the subject or (ii) yields useful knowledge about a subject's problem or disorder. In the latter case, both parents must give consent. If a child is a ward of the state, the HSRC must require that there be an advocate appointed to function as a guardian in the child's behalf.

Research With Minors Persons With Mental Disabilities

Persons with mental disabilities also require special consideration. They may or may not be able to give consent depending upon the severity of their disabilities. If a person is capable of understanding the nature of the project, consent should be obtained from both the subject and a parent or guardian. In instances where the person is not competent to consent, parental or guardian consent alone is sufficient.

NAZARETH COLLEGE INFORMED CONSENT CHECKLIST

- O Header that includes Nazareth College of Rochester, the Department, title of research study, and researcher's names.
- O Written in the first person (e.g., I, me, my).
- O Language at a level appropriate for the participant (remembering that the mean reading level in the U.S. is 7th grade).
- O The nature, purpose, duration of the study, including that it is experimental.
- O Procedures to be employed in the experiment (i.e., exactly what the participants are expected to do).
- O Risks (hazards, inconveniences, discomforts) the subject may experience, as far as they are known and how any risks will be minimized.
- O The following statement: "As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken."
- O Benefits to the subject; state none if none; if general benefits expected, state those.
- O If experiment is therapeutically related, disclosure of alternate procedures the subject might choose.
- O Conditions of participation such as age, health status, etc.
- O How confidentiality will be maintained and any limits to confidentiality.
- O That the participant can withdraw her/his consent to the research or discontinue participation in the research at any time without prejudice or penalty.
- O Circumstances under which the PI may terminate subject participation without subject consent.
- O Contact person(s). Include the researchers' name and telephone numbers (students must include faculty advisor's name and telephone number) as well as the following statement: "The participant may also contact the Chair, Human Subjects Research Committee, Nazareth College, if questions or problems arise during the course of the study."
- O Place for date and signature of the participant; witness line should be included ONLY if required.
- O No language that would absolve the researcher of negligence.
- O If appropriate, that any significant new findings affecting risks will be reported to the participant.
- O If appropriate, debriefing procedures.