PROVISO MATHEMATICS AND SCIENCE ACADEMY

"A CATALYST FOR GREATNESS"

RESEARCH MENTORSHIP PROGRAM

INSTITUTIONAL REVIEW BOARD

GUIDELINES FOR RESEARCH INVOLVING HUMAN SUBJECTS

BACKGROUND

Informed consent is an ethical requirement of any research study conducted on humans. Horrific things have been done to humans by other humans in the name of scientific progress throughout our history. The Tuskegee Syphilis Study, begun in 1932 and lasting until the early 1970's, the work of Dr. Stanley Milgram at Yale University in the early 1960's, and the medical "experiments" conducted by the Nazi's during WWII, are but a few examples of what becomes possible when researchers lose their moral and ethical way. While such dangers can be marginalized due to the scale or scope, or to time passed, to do so is to ignore the teachings of the past. The AIDS virus, stem cell research, cloning, the disposal of nuclear waste, the colonization of space all represent significant problems that present ethical and moral challenges to our future.

The Nuremberg Code, established after World War II in response to the Nuremberg War Trials and the information that emerged from those proceedings, represents the first internationally recognized code of ethics that governs the treatment of human subjects in research studies. This code was voluntary, so within the United States, the National Research Act signed in 1974, created the National commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission was charged with developing the basic ethical principles that should ground all such research. Their findings, published in the Belmont Report of 1979, codified these principles around three basic areas, respect for persons, beneficence, and justice. The most current code for the protection of human subjects can be found in the Guidelines for the Conduct of Research Involving Human Subjects from the National Institutes of Health.

INFORMED CONSENT

Organizations such as the Academy that are dedicated to building the capacity of its students in design, conduct, and evaluation of research in a variety of fields of study have a moral and legal obligation to attend to the ethics of such work. To this end, the establishment of an Institutional Review Board, or IRB, to oversee all such work by both students and staff is imperative. PMSA's IRB must establish protocols and procedures by which all research is conducted. Membership to the board is by appointment by the Principal, who also chairs this group. Their obligation is to meet as often as is necessary to provide the support for student and staff research. The submission of the IRB Informed Consent Form is a requirement for all research studies conducted while at the Academy.

The concept of Informed Consent becomes of primary concern when conducting research with human subjects. The participant, or subject, of the research, must be given enough information to make a reasoned judgment regarding the possible risks and benefits to themselves if they choose to participate. They should know the purpose of the study, the methods used for data collection, their right to refuse or withdraw from the study at any time, and the assurances of privacy and confidentiality they can expect. The researcher has the full obligation to divulge this information to all potential subjects prior to the collection of any data. Failure to do so represents not only an ethical lapse, but may also bring with it the

complete collapse of their research study. Researchers must hold themselves to the standards and principles of ethical research, while the IRB provides the necessary structure to ensure full compliance for the protection of subjects.

In the era of collecting human subject research data using the internet, studies that utilize this methodology deserve special consideration. Email and web surveys allow for greater response rates and thus greater degrees of confidence (potentially) in the data. They also bring greater challenges with ensuring confidentiality and anonymity of responses, as well as with collecting informed consent. Given that much of the research conducted by students at the Academy is likely to be collected from other students, how can informed consent from a minor be gained? Two conditions are both possible and permissible:

- If the subject of the research is of a sensitive nature, involving issues related to drug use, sexuality, conditions of abuse, or other such conditions, informed consent that includes the consent of the parent or legal guardian is required. This decision rests with the IRB alone, so if in doubt, submission of the informed consent form will provide clarity.
- If the nature of the research is less sensitive, in that the risks posed to the subject by their participation are minimal, then the informed consent of the participant alone is sufficient. No parental consent is then required. The student researcher must ensure that all participants are informed of their right to withdraw from the study at any time and that they agree to participate in the study by actively checking a box on the survey to that extent. The language of the question that must appear on a survey is as follows:

  I understand the purpose of this research study and the nature of my participation. I also understand that I may withdraw from this participation at any time. By selecting the I AGREE box on the question below, I agree to participate in this study.

In all cases, the student researcher must submit the informed consent form to the IRB for approval. Once given, proceeding using either of the two conditions above is permissible.

REFERENCES

Guidelines for the Conduct of Research Involving Human Subjects, 5th Printing, August 2004. Washington D.C.; U.S. G.P.O. 00-4783

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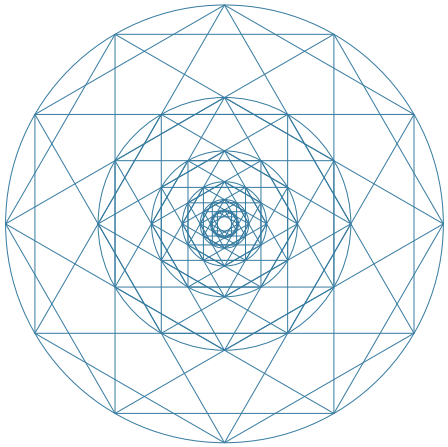
Research Approval Protocol



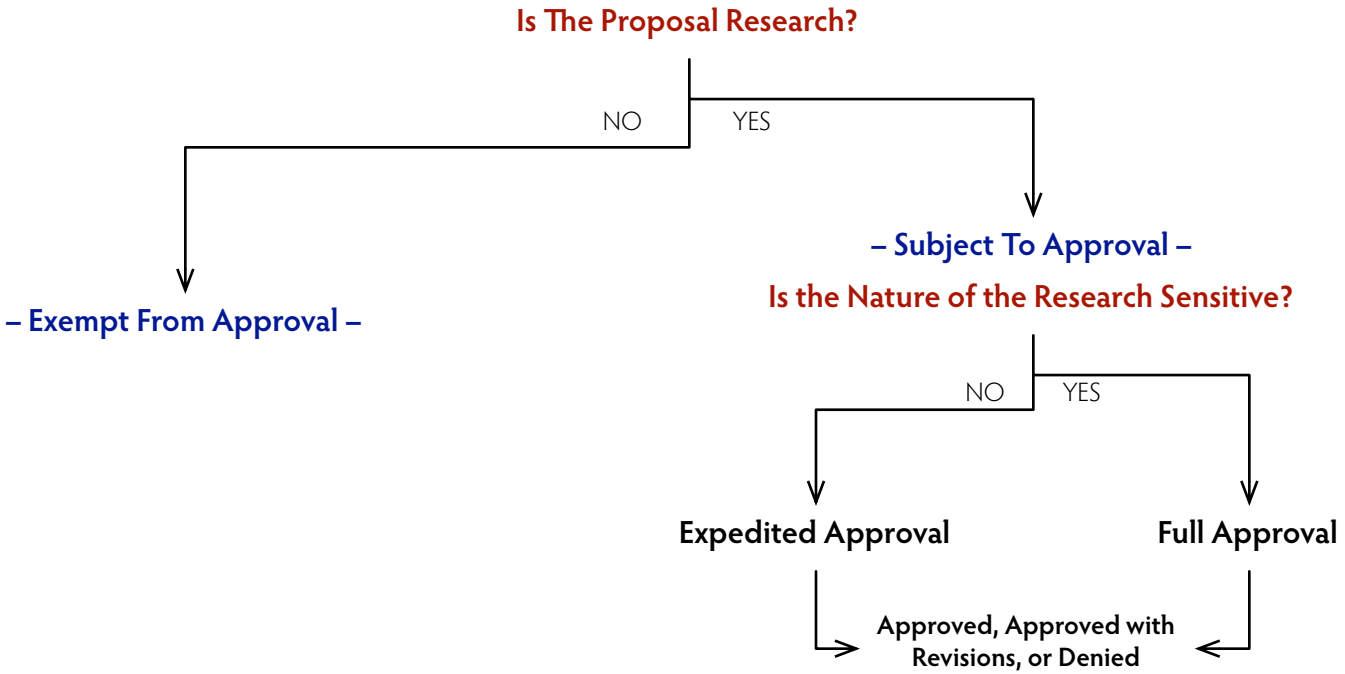
Research Defined

A SYSTEMATIC investigation into a question whose answer may be GENERALIZABLE to broader contexts or populations.

Institutional Review Board (IRB) Defined

An empaneled group of community members whose charge is to ensure that ethical practices are followed for all research studies conducted within the Academy program.

All Research Proposals Are Submitted to IRB



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RESEARCH MENTORSHIP PROGRAM
IRB INFORMED CONSENT or AGREEMENT TO PARTICIPATE FORM

Informed consent is an ethical requirement of any research study conducted on humans. Enough detail about the study and its possible impact on the human subject must be given so that the individual or guardians can make an informed decision regarding participation. This form must be submitted to the PMSA Institutional Review Board and supplied to potential subjects before any collection of data.

Purpose of Study

Procedure and Duration of Study

Potential Risks or Discomfort to Subjects

Incentives or Compensation to Subjects (if any)

Anticipated Benefits to the Subject or to Non-Subjects

Right to Refusal or Withdrawal of Participation

Assurances of Privacy and Confidentiality

Additional Information, Including Contact Information of Researcher(s)

Signed: _____ Date: _____

Student

Signed: _____ Date: _____

Mentor

Signed: _____ Date: _____

IRB Chair/Principal

I have read and understand the purpose of this study and the potential risks and/or discomfort, if any, that my participation might bring. I have also had an opportunity to discuss my concerns and questions with the researcher. I give consent for my involvement in this research study.

Signed: _____ Date: _____

Participant

Signed: _____ Date: _____

Participant Parent, Guardian, or Legal Representative, If Necessary

Parent Permission (if necessary): I have read and understand the purpose of this study and the potential risks and/or discomfort, if any, that the participation of my child might bring. I have also had an opportunity to discuss my concerns and questions with both my child and the Research Core instructor and I give my consent for his or her participation.

Signed: _____ Date: _____

Participant Parent, Guardian, or Legal Representative, If Necessary