Le Moyne College
INSTITUTIONAL REVIEW BOARD (IRB)

Policies & Procedures
for the
Protection of Human Subjects

INSTITUTIONAL REVIEW AND APPROVAL

All research involving human subjects which is not explicitly determined to be exempt (see below), conducted at Le Moyne College, or under its sponsorship at another location, **must** be reviewed and approved by the Institutional Review Board for the Protection of Human Subjects (hereinafter referred to as the IRB. Review is also required for research carried out under the sponsorship of an institution other than Le Moyne College, but which is to be performed on the premises of Le Moyne College, even if the research has already been approved by the IRB at the sponsoring institution or elsewhere.

These policies covering all human subjects research at Le Moyne College result from:

a. The College's self-imposed commitment, based in its fundamental mission and values, to equally safeguard the rights and welfare of human participants in all instances of research under its sponsorship and to serve as their protector on behalf of the community of persons of which the College is a part.

b. The desire of the College to comply with federal regulations concerning the establishment of such a board (See Title 45, Part 46 of the Code of Federal Regulations) (CFR) .

c. The recognition that professional journals and other media of professional communication increasingly require that published reports based on human subject research have IRE approval.

d. The need for the College to reasonably manage institutional risk.

The IRB, whose goal is the safeguarding of the rights and welfare of individual research participants, is to provide an independent determination concerning whether research participants are placed at minimal risk (defined below) or qreater than minimal risk; and, if greater than minimal risk is involved, to assure that:

1. the risks to the subject are substantively outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained so as to warrant a decision to allow a subject, who has been properly informed of the potential risk (see discussion of informed consent below), to accept such risk.

2. legally effective informed consent will be obtained by adequate and appropriate means;

3. the conduct of the activity will be reviewed at timely intervals.

Research covered by this policy that has been approved by the IRB may be subject to further review by officials of the College (for example, in the case of application for external funding see Le MoyneColleqe Policies and Procedures for External Fundinq). However, those officials may not approve the research if it has not been approved by the IRB or if written assurances have not been provided that it will be submitted for review at the next scheduled IRB meeting.

DEFINITIONS

Activities within the scope of the IRB's responsibilities include research, development, and related activities which would normally be construed as biological, behavioral, or psychological investigations involving human subjects. Included are studies involving not only adults and children, but also investigations of prenatal life and the deceased. Studies or procedures utilizing organs, tissues, or bodily fluids of a human being are also included, as are the use of graphic, written, or recorded information about individuals even when this information has been collected by other institutions or investigators.

For the purpose of the IRB review, Le Moyne College stipulates the following definitions:

Research -Research is any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for the IRB, whether or not they are considered research in other contexts. Excluded from this definition are activities whose purpose is instructional; also excluded are activities whose purpose is related to routine course or program development. However, when such research activities involve subjects drawn from outside of the course, the instructor should follow the procedures outlined below for exemption from review, expedited review and formal review.

Research activity would normally include the following:

1. Persons or programs requesting extramural (federal, state, or private) funds for research or training.

2. Individual faculty members as well as members of the staff and administration engaged in research as part as their professional role within the College or as part of their job assignment.

3. Students doing research which is of the nature of a thesis and is part of a degree program.

4. Students performing research as part of an independent study or the Honors Program.

5. Individuals (including students or persons from outside the College) other than faculty, staff, or administration, conducting research at Le Moyne College.

Minimal Risk -Minimal risk exists when the probability of and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (see 45 CFR 46.102(i)) (Investigators have the obligation to request a clarification by the IRE when there are any questions regarding whether planned activities or procedures involve only minimal risk.)

IRB Approval -Approval means that the IRB has reviewed the research and that the research may be conducted at Le Moyne within the policies and procedures outlined in this document and within the constraints of other institutional and federal requirements. IRB approval does not necessarily imply approbation for the research itself.

SCOPE OF IRB REVIEW

A. Research Exempt From Review

Investigators conducting human subject research exempt from IRB review shall give notice to the IRB chairperson of such research on Form A: Notice of Exempt Research, which will require a statement that the research is in one of the following categories:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemicalor environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(4) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(5) Research involving the unobtrusive observation (including observation by participants) of public behavior, except where any of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(6) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) surveyor interview procedures, except where any of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could

reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol, (iv.) the surveyor interview involves children or respondents requiring supervision, e.g. mentally retarded adults. All research involving surveyor interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

E. Expedited Review

The IRB may review some research through an expedited review procedure, if the research involves no more than minimal risk. This procedure is initiated by the filing of an Application for Expedited Review, which is attached as Form E, and the review may be carried out by the IRB Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the IRB. In reviewing the research, the reviewers mav exercise all the authority of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the full formal review procedure set forth below. The Chairperson shall inform all IRB members of research proposals approved under the expedited review procedures.

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through the expedited review procedure (please note that instances 1 through 4 are most relevant to Le Moyne College):

1. Voice recordings made for research purposes such as investigations of speech defects.

2. Moderate exercise by healthy volunteers.

3. The study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the individual from whom the data were collected are identifiable.

4. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve- stress to subjects .

5. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

6. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

7. Recording of data collected from subjects 18 years of age or older in the course noninvasive procedures routinely employed by professionally certified/licensed individuals in the clinical practice of medicine, psychology and social work. This includes the use of physical practice sensors

that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electro-encephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example x-rays, microwaves) .

8. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

9. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routing prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

C. Full Formal Review

Application for full formal review may be made to the IRB through the submission of a completed "IRB Form C: Application for Review of Research," a Research Description (described below) and an informed consent form (see Section VIII), unless the investigator believes the proposed research meets the criteria for exemption from formal review or expedited review. A copy of Form C is attached and is also available from the Chair of the IRB. A new application for review is required for each research project that differs significantly in terms of procedures or subject populations from a previously approved application.

The ultimate determination of whether subjects are at greater than minimal risk and therefore require Full Formal Review can be made only by the IRB. If, however, the investigator believes subjects will be placed at more than minimal risk (as defined above), then the IRB must approve the Research Description and the required informed consent form to be used. The IRB must approve both the form and the procedure by which consent is to be obtained. It is the policy of the IRB to require an informed consent for any study involving children (under 18 years of age) and other vulnerable populations, no matter what the condition of risk. The procedures necessary for a proper informed consent are described below; examples of approved informed consent forms for adult subjects and parents of minor subjects are attached as Forms D and E, respectively. When reviewing research proposals, the IRB is primarily interested in safeguarding the rights and well-being of the human subject and in assessing the ethical implications of the proposed procedures.

When reviewing Research Descriptions, the IRB may pass judgment on "research design," but only to the extent that such design affects the rights or well-being of human subjects. In analyzing the risk/benefit ratio of a research activity, both the stated goals and the scientific merit of the research will be considered. If the IRB's analysis reveals serious flaws in the research design that influence the risk/benefit ratio of the proposed research activity, the IRB Chairperson or an experienced member of the IRB will consult with the investigator with the goal of clarifying the concern and resolving it. For these reasons it is essential that the research be described to the IRB in a manner that allows adequate review of all these aspects of the research.