I. Institutional Commitment

Guided by its Catholic and Dominican tradition, Molloy College is committed to safeguard and respect all human subjects invited to participate in research by faculty members, students or other users of college facilities, regardless of where the research is conducted. Subjects must be treated as intrinsically valuable agents (both competent or with diminished capacity) who are due protection from risk of injury or from violations of their privacy or right to confidentiality. The college’s commitment accords with the principles guiding the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979):

1. “Respect for Persons. The principle of respect for persons…divides into two separate moral requirements; the requirements to acknowledge autonomy and to protect those with diminished autonomy.
2. Beneficence. Two general rules have been formulated as complementary expressions of beneficent actions: (1) do no harm and (2) maximize possible benefits and minimize possible harms.
3. Justice. Who ought to receive the benefits of research and bear its burdens? This is a question of justice in the sense of ‘fairness in distribution’ or ‘what is deserved.’ An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.”

In accord with the principle of Respect for Persons, informed consent must be obtained from the research subject, unless the research falls within an exempt category as defined below. Care must be taken to fully apprise the subjects about what their participation in the research entails, the nature of the research and its purpose, any risks or discomforts they might experience and how their privacy and the confidentiality of personal information will be protected. Subjects must be entirely free to refuse to participate in the research or to withdraw from the research for any reason at any time. Coercive pressure (including excessive material enticements) must be entirely absent from any attempt to recruit research subjects, their compliance with the terms of the study or their commitment to remain in the study. Research involving subjects with diminished autonomy cannot proceed without the proxy consent of the subject’s legal guardians, subject to the approval of the Molloy Institutional Review Board (IRB).

In accord with the principle of beneficence, risks to the subjects are to be minimized. Researchers are obligated to assess the potential risks and benefits to the subjects of their study. Subjects must be fully informed of these risks and benefits and no study should proceed that involves risk of harm disproportionate to the
benefits received by the subject or to society. However, social utility, even of great magnitude, never justifies the suspension of the rights of individual subjects or of the obligation of researchers to protect them from the risks of significant harm.

Justice means giving to persons what they are owed or due as persons. Justice demands a fair and equal opportunity of subjects to participate in research studies and to benefit equally from the consequences of that research.

II. The Role and Function of the Molloy Institutional Review Board.

Molloy College’s Institutional Review Board has been constituted to ensure the safety, rights and welfare of all human subjects enrolled in research authorized by the college.

IRB approval must be obtained for the following:
1. All research conducted by or under the direction of a Molloy College employee, whether the research is funded or non-funded, or any research conducted by, or
2. under the direction of a Molloy College employee utilizing Molloy property, personnel, students or facilities, or
3. any research that utilizes the institution’s non-public information to identify or contact human research subjects or prospective subjects.

It is the responsibility of the IRB to:

• Ensure that the risks of research to a subject are minimized and are outweighed by the potential benefits to participants and or to society by the importance of the knowledge to be gained.
• Require that adequate and appropriate informed consent is obtained from subjects
• Monitor compliance by researchers of agreed upon protection of human subjects through periodic review
• Guarantee that all research under its purview conforms to the Department of Health and Human Services Regulations for the protection of human research subjects, to all federal, state and local laws, and to the principles and guidelines of the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979).
• Review annually or at its discretion all ongoing human subject research conducted under the purview of Molloy College.

The IRB consists of nine members, six of whom volunteer from the following departments: The Office of Academic Affairs, a Social Science Department (Psychology, Sociology, Social Work, Criminal Justice, Education, or Economics), Ethics (Philosophy or Theology), Physical Sciences (Biology, Earth Science, Chemistry, Nursing), with at least one member from each of the groups. This will ensure that members with
appropriate expertise in the areas of biology, sociology, psychology, law, ethics, and theology should be represented on the IRB. The IRB also includes three members from institutions that are not affiliated with Molloy College. Membership should reflect the multi-cultural, gender, racial and ethnic diversity of the Molloy College community. The members will be appointed by the Vice President for Academic Affairs from the volunteers for a term of four years, renewable once. A new IRB will commence on the date that the new IRB policy takes effect. Four members will serve for a period of two years from that date and four members will serve for a period of four years. Thereafter all members will serve for a period of four years. Terms for both members from the Molloy community and members from other institutions will be staggered. The Chair of the IRB is elected by the members.

The IRB will meet with the Vice President for Academic Affairs at least once each academic year. All records of the IRB will be kept in the Office of Academic Affairs. This will be the responsibility of the member from Academic Affairs.

Voting: Decisions concerning the category of proposals (Exempt, Expedited, or Full Review) will be determined by consensus of the Chair and two other committee members (rotated among the membership). For Expedited status, the Molloy members of the committee will make the determination whether to approve by a majority of the membership. For Full Review status, the decisions of the IRB will require a majority agreement of the entire IRB membership.

The IRB may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Other than research exempted from Molloy IRB regulation as listed below in Section III, all Molloy sponsored research, funded or non-funded, involving human subjects must adhere to the policies and procedures promulgated by Molloy through its IRB.

Researchers must submit an application for approval to the IRB and must not include human subjects in the research until approval has been given. Thereafter, review applications must be submitted annually or when requested, until research is completed. Any changes in the research scope or mode of inquiries to subjects must be reported and receive additional approval by the IRB before implementation. A copy of the research results must be supplied to the IRB Chair for record purposes.

Violations are considered a serious breach of professional standards and of the mission, objectives, and values of Molloy as a college in the Catholic and Dominican tradition. Violations of Molloy’s Human Subject policy may result in IRB referral to the Vice President for Academic Affairs for consideration of sanctions against researchers to be imposed by Molloy College. Substantiated complaints may result in IRB refusal to consider any subsequent research of such faculty. Outside investigators engaging in scientific or human rights misconduct will be reported to their supervisors at their host
institutions and their relationship with Molloy College will be severed. Student violators will be referred to the Associate Dean for Academic Support Services.

Molloy reserves the right not to defend investigators should litigation result from violations in connection with their research activities in circumstances where the investigator has failed to submit a research protocol for the required IRB approval, or, having submitted such a protocol, the investigator departs substantially from the approved research protocol or fails to implement the required emendations and/or alternative procedures.

Molloy’s IRB reserves the rights to suspend, take possession of, or destroy research that does not, in its judgment, conform to IRB requirements, guidelines or regulations.

III. Categories of Review *see Addenda for further explanation

Research involving human subjects has been divided into three separate categories, each of which will be reviewed by a different process.

1. Exempt (determined by an IRB member)
2. Expedited (requires review by several IRB members, not full Board)
3. Full Review (must be reviewed by all IRB members)

The final decision about which category a particular project is in rests with the Institutional Review Board.

The agencies that fund research may require the submission of an Institutional Assurance. Researchers should ensure that the information submitted to the IRB is sufficiently detailed to allow a determination of the category of exemption to be made. The grant agency and number (if known) should be provided.

IRB reserves the right to review any project, even if it falls within the exempt categories, and to overrule any departmental approval involved, if necessary. Departments should refer all projects to the IRB.

Exempt Categories

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review.

   a. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

   b. Research involving survey or interview procedures, except where any of the following conditions exist:

      (1) Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.
(2) 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, and

(3) The research deals with sensitive aspects of the subject’s own behavior, such as, illegal conduct, drug use, sexual behavior, or use of alcohol.

c. Research involving the observation (including observation by participants) of public behavior, except where any of the following conditions exits:

(1) Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.

(2) 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, and

(3) The research deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

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

**Expedited**

Research, which involves no more than minimal risk and falls within the categories listed below, will be reviewed by expedited review. ‘Minimal risk’ means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than in those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Researchers should submit their applications to the IRB. The researcher should ensure that the project is scientifically sound and that the procedures and likely risks are adequately described. When IRB acceptance of the Expedited category has been obtained, the original plus three copies of the application should be submitted to the IRB.

Expedited review will be carried out by at least three members of IRB including:

(1) a member from a related discipline;

(2) a scientific member;

(3) a non-scientific member.

Researchers will be notified if the IRB approves; such approval is valid for a period of 12 months, unless otherwise specified.
**Expedited Categories**

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

b. 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.

c. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical 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, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography.

d. Collection of both supra and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic and aseptic techniques and using "universal precautions".

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

f. Moderate exercise by health volunteers.

g. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

h. 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.

i. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

**Full Review**

All other research, i.e., non-exempt, non-expedited, will be reviewed by the Committee at one of its monthly meetings. Dates of meetings can be obtained from the IRB Chairperson of Molloy College.

The application should be submitted to the IRB Chair at least ten days prior to a Committee meeting. Applications submitted after this time will be reviewed at the following meeting.

If the research is externally funded, or external funding is being sought, three copies of the full grant application should also be submitted. If possible, IRB applications should be submitted early enough so that the Institutional Assurance can be submitted with the grant application.
Researchers will be sent a copy of the IRB approval and any Institutional Assurance submitted. IRB approval is valid for one year, unless otherwise specified.

IV. Special Concerns of the IRB

The Molloy IRB will pay special attention to three aspects to be made explicit in the application for IRB approval:
   A. Informed Consent
   B. Confidentiality
   C. Risk/Benefit assessment

A. Informed Consent

Informed consent is vital to the ethical conduct of research involving humans. Even research involving minimal risks to subjects violates their intrinsic dignity as autonomous persons in the absence of informed consent. No coercive persuasion or exorbitant incentives can be utilized and no “tacit” or “passive” consent” is to be assumed by researchers.

When subjects are children (under 18) or not competent to consent the parent or legal guardian must sign the consent form.

So central is the concept of informed consent that the DHSS guidelines are herein included:

In seeking informed consent the following information shall be provided to each subject:
   a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
   b. A description of any reasonably foreseeable risks or discomforts to the subject;
   c. A description of any benefits to the subject or to others which may reasonably be expected from the research;
   d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
   e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
   f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
   g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects; rights, and whom or contact in the event of a research-related injury to the subject; and
h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional conditions for approval:
- The informed consent document should be written in language understandable to the subjects. If the subjects are non-English-speaking, the document should be translated.
- Where the potential need to report illegal activity to the authorities exists (e.g., child abuse, drug and alcohol abuse by minors), the subjects should be so informed before agreeing to participate.
- Where there is reason for special concern (e.g., regarding pressure on potential subjects), the IRB may require monitoring (such as a third party observer).
- Subjects should be given a copy of the consent form as a reminder of the information conveyed.
- Consent forms must be retained for at least three years following the conclusion of a research project.
- If vulnerable populations are involved, additional safeguards are generally required. In the case of children, in addition to the required parental/guardian consent, an “assent” document should be prepared, written in language the child will understand.

B. Confidentiality and Privacy

As rational autonomous agents our dignity consists, in part, in having substantial control over the sharing of personal information about our physical, psychological, behavioral, intellectual or emotional lives. Researchers who reveal to others unauthorized non-public information about research subjects harm the dignity and violate the privacy rights of those subjects. Consequently, researchers are required to assure the maintenance and the security of the information that the subjects authorize them to gather in the course of a research project. Further, potential subjects must be allowed to refuse participation in a non-exempt study before their identity or means of contacting them is revealed to a researcher.

The promise of confidentiality should be conveyed in writing to the research subject or to the proxy and to the IRB. Researchers should take advantage of well-designed security measures to ensure their confidentiality vow to subjects. These include the use of codes, storage of data under lock and key, and certificates of confidentiality (cf. Public Health Service Act, Section 303 (a), (42 USC 242 a (a).

Where appropriate, researchers must abide by HIPAA (Health Insurance Portability and Accountability Act of 1966) standards.
C. Risks/Benefit Assessments

Applications to the IRB must include an assessment of potential risks to benefits and a statement of possible benefits, if any, to the subjects or the importance of the knowledge that may reasonably be expected to result.

The IRB should fully inform itself of any physical, psychological, social or economic risks that research participants may face. It is the responsibility of researchers to minimize risks to subjects. The design of the research must include precautions, safeguards and alternatives to protect subject from unnecessary dangers.

Further the IRB will examine whether the risks are reasonable in relation to the foreseeable benefits. Special consideration will be taken when proxy consent is sought for subjects who are children or persons of diminished capacity. Subject populations who are particularly vulnerable to risks such as pregnant women, terminally ill subjects or the frail elderly deserve heightened oversight. Care must be taken not to allow social utility of even great magnitude to justify subjecting subjects to grave risks or to violate their rights to privacy, confidentiality or informed consent.

In non-therapeutic experiments where no benefits to the subject are anticipated, the IRB must evaluate whether the risks presented are ethically acceptable.

V. Monitoring Ongoing Research

Ongoing research involving human subjects will require a submission of the application for Renewed IRB Approval every twelve months after the commencement of the research. The application must include any changes in the experiment or study and any change in the type or probability of risks to the subjects. The IRB reserves the right to review the study more frequently depending on the degree of risk involved in the study. Researchers should reapply one month in advance of the expiration of the current approval date. Failure to renew will automatically result in termination of IRB approval of the research.

VI. Reporting adverse consequences

The Researcher is obligated to immediately and fully report any adverse effects to subjects that occur during the course of the study to the Office of Academic Affairs who will communicate them to the Chair of the IRB.

VII. Applications
Applications to the IRB must contain:
   a. Completed Research Application form
   b. A one or two page description of the proposed research project
   c. Any consent forms that will be used
   d. Grant application when appropriate

All applications must be submitted as one e-copy and one hard copy, submitted to the Chair of the IRB.

VIII. Student Research Guidelines

Students in certain courses are taught professional research methods which may involve human subjects. As a part of this instruction, students need to learn the principles and policies governing research involving human subjects. Therefore, prior to the beginning of the research project these should be reviewed to ensure that the rights and welfare of human subjects are protected.

Course instructors have the primary responsibility for ensuring that the rights and welfare of human subjects are not violated. This responsibility includes:
   Communicating to students the ethical principles for the protection of human subjects
   Reviewing student research protocols
   Monitoring research activities and reports of findings.

If student research involves passive observation of public behavior, poses no more than minimal risk, and subjects will remain anonymous or their identity will be kept confidential, instructor’s approval of the research is sufficient; informed consent of subjects is not required.

If student research includes involvement of the human subjects (e.g. use of tests or surveys) but poses no more than minimal risk, and subjects will remain anonymous or their identity will be kept confidential, informed consent is required, in addition to the instructor’s review and approval of the research and approval of the IRB. If the student research is generic (i.e., all students will use the same instruments, methods, and consent procedures), the instructor may submit one IRB application form which will apply to all student researchers in that course until the protocol or conditions of research are changed, or unless there is a complaint from or adverse reaction by a subject.

IX. The IRB reserves the right to review and change this document as it sees fit.

April 14, 2004
Revised Sept. 16, 2004
Revised Feb. 9, 2011
Addenda:

*Exempt category:* Refers to proposals that would not harm the human subjects, which must be determined by the IRB. A minimal number of IRB members review these proposal to determine that they are indeed exempt from further review.

*Expedited category:* Refers to proposals which involve only minimal risk. This is also determined by the IRB. At least three members of the IRB review these proposals. "Expedited" in this context does not mean that the review will be rushed; only that it does not require review by the full Board.

*Full Review:* Refers to proposals that must be reviewed by all the IRB members and discussed at an IRB meeting.