Long Island University
INSTITUTIONAL REVIEW BOARD

GUIDELINES FOR INVESTIGATORS

(Including University Policy, Application Forms, and Procedures for Obtaining Approval)

OFFICE OF THE VICE PRESIDENT FOR ACADEMIC AFFAIRS

APRIL 2013

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INTRODUCTION

These guidelines are an elaboration of Long Island University policy. This policy, provided in Appendix A, applies to all University faculty, staff, and students using University facilities, the facilities of another institution, or any other off-campus site. The policy also applies to visitors and users of the campus or off-campus University facilities.

Long Island University has a Federal-Wide Assurance (FWA 00002562) on file with the Office for Human Research Protections (OHRP; subdivision of the federal Department of Health and Human Services). This document provides a written assurance that all research conducted at Long Island University that involves human subjects will be in compliance with the Federal Policy for the Protection of Human Subjects, specifically 45CFR46 and 21CFR56. (Note: CFR is the Code of Federal Regulations)

The basic ethical principles that underlie the Federal Policy are summarized in the Belmont Report. These regulations have been adopted by Long Island University to cover ALL research activities involving human subjects, regardless of the source of funding.

Long Island University has two Institutional Review Boards (IRBs), one at the LIU Brooklyn and one at the LIU Post. The IRBs are charged with the responsibility of protecting the rights and welfare of human subjects involved in research, as mandated by OHRP, the Food and Drug Administration, and the State of New York. The makeup of the IRBs membership and the number of members on the committee is in accordance with the Federal Policy. These are the only designated Institutional Review Boards for Long Island University.

Members of the Institutional Review Boards are appointed by the Vice President for Academic Affairs (the Institutional Official), as designated on the Federal-Wide Assurance, following consideration of recommendations from Deans, Chairs, Provosts, current members, the Assistant Vice President for Sponsored Research, and/or members of the community (for non-University positions). Members are appointed for a renewable three-year term. All members have full voting rights; no proxy voting is permitted. Attendance records and member contributions to the committee are reviewed by the IRB Chair, the Assistant Vice President for Sponsored Research (IRB Executive Secretary), and the Vice President for Academic Affairs, to determine if appointments will be renewed. Appointments of the Chair are made by the Vice President for Academic Affairs. There is no remuneration for individuals serving as IRB members. No IRB member participates in the review of any study on which s/he is an investigator or co-investigator or where a potential for conflict of interest exists.

The Institutional Official, or his/her designee, conducts an orientation for new members in which relevant materials are provided (Belmont Report, federal regulations, University Policy, IRB Guidelines, etc.), and the details concerning committee function and

procedures are discussed. The new member attends at least two IRB meetings for the purpose of observation, without participating in the review of studies.

The IRB may, at its discretion, invite individuals with competence in special areas (consultant) to assist in the review of complex issues that require expertise beyond, or in addition to that available on the committee. The consultant does not take part in voting with the committee. Similarly, investigators may request, or be invited, to attend IRB meetings to clarify issues with the members concerning their proposed research activity. Such guests do not take part in committee deliberations or voting.

The IRB reports to the Vice President for Academic Affairs. The Executive Secretary who is a non-voting member of the committee, serves as the liaison between the research investigators and the IRB. The Executive Secretary and Secretary provide administrative and secretarial support for the committee, and assists the investigators through the application and approval process. S/he acts on behalf of the committee and the University when providing assurance of human subjects' approval to sponsoring agencies, or when dealing with regulatory agencies. S/he is responsible for monitoring the IRB's compliance, and updating IRB procedures with current and/or new relevant federal or state regulations.

Correspondence (including application materials) to the IRB may be directed to:

Secretary, IRB
University Office of Sponsored Research
Bush Brown Hall, Room 207
University Center
Long Island University
700 Northern Boulevard
Greenvale, NY 11548

SECTION 1
DEFINITIONS

A. Research
A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

B. Human Subject
A living individual about whom an investigator conducting research obtains data directly, through intervention or interaction with the individual or indirectly, through study of the individual's existing data and/or biological specimens.

B. Minimal Risk
The probability and magnitude of harm or discomfort that is anticipated in a research activity are not greater, in and of themselves, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.

SECTION 2
CATEGORIES OF RESEARCH REQUIRING IRB APPROVAL

A. Exempt Review Category
Research in this category is considered exempt from full committee review and follows the federal definitions for exemption. However, the IRB requires that such activities be on file and be issued an approval date so that the status of the research may be reviewed on a continuing basis. A copy of the request for exemption will be made available to all IRB members at a regularly scheduled meeting of the committee.

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

2. Research involving the uses of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.
   UNLESS **ALL** OF THE FOLLOWING CONDITIONS EXIST:
    - Information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, AND
    - Any disclosure of the human subjects' response outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under #2 above if:
    - The human subjects are elected or appointed public officials or candidates for public office, OR
    - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

5. Research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine (a) Public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) 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 chemical or 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.

Exempt Review Procedures: The investigator(s) may request exempt review by submitting the LIU Exempt Request form (Appendix B, Forms). If it is determined that an application falls into the exempt category, the primary reviewer may be the Executive Secretary. Once the review has been completed, the investigator will be notified by memo from the Executive Secretary on behalf of the committee regarding the status of the application. Notification will indicate either that the application was fully approved based on the exempt category or that modifications/clarifications are required or that a full application must be submitted for full committee review. A copy of the application and findings will be made available to all IRB members at a regularly scheduled meeting.

B. Expedited Review Category

Research activities that present no more than minimal risk to human subjects, AND involve only procedures in one or more of the following categories, as defined in the

federal regulations, may be reviewed using the expedited review procedures described below. The categories apply regardless of the age of the subjects except as noted.

Expedited review is NOT permitted when identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing. The IRB may review minor changes to research approved by the full committee via expedited review. (A minor change is one that has no substantive effect upon the protocol risk already approved by the full committee as being acceptable research risk.)

1. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. (Examples of noninvasive procedures: physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; weighing or testing sensory acuity; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.)

2. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes such as medical treatment or diagnosis.

3. Collection of data from voice, video, digital, or image recordings made for research purposes.

4. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

5. Clinical studies of drugs and medical devices only when the following conditions are met:
    - Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) AND
    - Research on medical devices for which an investigational device exemption is not required, OR the medical device is cleared/approved for

marketing and is being used in accordance with its cleared/approved labeling.

6. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    - From health, nonpregnant adults who weight at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; OR
    - From other adults and children (under 18 years old) considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

7. Prospective collection of biological specimens for research purposes by noninvasive means. (Examples: hair and nail clippings in a non-disfiguring manner; excreta and external secretions; deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction.)

8. Continuing review of research previously approved by the full committee as follows:
    - The research is permanently closed to the enrollment of new subjects;
    - All subjects have completed all research-related interventions; and
    - Research remains active only for long-term follow-up of subjects; or
    - Where no subjects have been enrolled and no additional risks have been identified; or
    - Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Expedited Review Procedures*:* The investigator(s) must submit a full application but may request expedited review (Appendix B, Forms). The review may be carried out by the Chair of the IRB and/or by one or more experienced reviewers chosen by the Executive Secretary from among the IRB members. In reviewing the research, the reviewers may exercise all the authorities of the IRB except that the reviewer(s) may not disapprove the research (disapproval may only be decided at a meeting of the full committee). Once the review has been completed, the investigator will be notified by memo from the Executive Secretary on behalf of the committee regarding the status of the application. Notification will indicate that the application was fully approved, that it required modifications/clarifications in order to secure approval, or deferred for

full committee review. A copy of the application and findings will be made available to all IRB members at a regularly scheduled meeting.

The expedited review category, and corresponding review procedure is applicable to research involving minor subjects, as long as the particular activity does not require that the subject be 18 years old or older.

C. Full Review Category
All research not noted above will be reviewed by the IRB at one of its convened meetings. The schedule of meetings is available from the Assistant Director of the Office of Sponsored Research and online from the Office of Sponsored Research's website.

1. A **quorum** (majority) of members, including at least one non- scientific member, must be present for a meeting to be held.

2. Copies of all applications to be reviewed at the meeting are distributed to the members approximately 10 working days before the meeting.

3. Each application is assigned a primary reviewer who presents the application and begins the committee deliberations; each member is responsible for reviewing each application.

4. After the meeting, the investigator is notified by memo from the Secretary on behalf of the committee regarding the status of the application. The application may be approved, requires clarifications/modifications in order to secure approval (conditional approval); deferred (i.e., response from investigator must be brought back to full committee), or disapproved.

Full Review Procedures: The investigator(s) must submit a full application (Appendix B, Forms). The review will be carried out as noted above.

SECTION 3
MATERIALS REQUIRED FOR APPLICATION TO THE IRB

Research activities that involve human subjects must be on file with the IRB and must be approved PRIOR to the commencement of the activity. Only one original copy of the application is required to be submitted regardless of the category of review. Note: The IRB will determine if a different category is applicable than the one indicated by the investigator.

A. IRB Full Application
The application must be complete with the following original signatures:

1. The investigator, who ensures accuracy of the information contained within the submitted materials and, upon approval, assures compliance with all aspects of Section IV, "Responsibility of Investigator Conducting IRB Approved Activities";

2. The Chair of the department, who certifies that the activity as scientifically meritorious and that the investigator(s) have the expertise required to carry out the protocol; and

3. If applicable, signature of the faculty supervisor of the student investigator. The supervisor assumes complete responsibility for the student's research including a) ensuring accuracy of the information contained within the submitted materials and b) assuring compliance with all aspects of Section IV, "Responsibility of Investigator Conducting IRB Approved Activities".

B. Project Description

This section clearly discusses, in LAY LANGUAGE, the research protocol. In addition to detailing all procedures in which human subjects are involved, the following must be included.

1. Discussion of the scientific significance and goal of the study.

2. Description of subject recruitment procedures, including copies of all advertisements, posters, scripts, etc. to be used.

3. Inclusion/exclusion criteria for subject enrollment. It is federally required that the application include specific justification if women, minorities and/or minors are to be excluded in the research activity.

4. Disclosure, if the investigator proposes to include him/herself, or members of his or her family as subjects in the proposed research.

5. Potential risks and benefits to subjects.

6. Highlights of potential problems related to risk/benefit, confidentiality, or other ethical problems.

7. Copies of all interviews, surveys, questionnaires, data collection forms, etc. to be used during the course of the project.

C. Sponsor Protocol

When funding is being sought or has been approved by an external agency (NIH, NYS Education, pharmaceutical company, philanthropic organization, etc.), the grant or sponsor protocol should be submitted in addition to (not in lieu of) the project description. Regardless of the review category, one copy of the grant or sponsor

protocol must be submitted if it is not currently on file with the Office of Sponsored Research.

D. Consent/Permission/Assent Forms

These should be on departmental letterhead and standardized to conform to the IRB required format (see Section 13). Note that **consent forms** are used to consent subjects 18 years or older, **permission forms** are used to obtain permission from parents of subjects 17 years or younger (since the subjects themselves cannot consent to being in the study), and **assent forms** are used to obtain agreement from the minor subject in the study.

For those consent forms that must be translated into a foreign language, an affidavit of accurate translation must be provided from an appropriate translator who is unaffiliated with the study (see Section 12).

For those studies where minors will be included, the IRB may (rarely) waive the need for a parent permission form **and** minor's assent as a condition for approval. However, these documents will still need to be submitted for review and approval prior to enrollment of minors in the study (see Sections 10 and 12).

SECTION 4
REVIEW TIME CONSIDERATIONS

The length of time required for **review** of an application by the IRB is dependent upon the review category into which an application falls. Expedited reviews are sent to committee members on a regular basis and the time required for review is dependent upon the availability of the IRB members. **Review** (not full approval) is generally completed within 2 weeks of receipt date.

The deadline for applications requiring full committee review at a convened meeting of the IRB is at least 10 business days prior to the meeting date. This allows for distribution of the application to the committee members as well as members' review time prior to the full meeting. Exact meeting dates can be obtained from the Secretary of the Institutional Review Board in the Office of Sponsored Research of from the Office of Sponsored Research's website. For research in which outside funding is involved, it is recommended that the IRB materials be submitted far enough in advance of the grant submission deadline or start date to allow for at least two (2) successive meetings of the IRB (in case of deferral).

SECTION 5
CRITERIA FOR IRB APPROVAL OF RESEARCH

In order to approve a research project, the Institutional Review Board must determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

3. Selection of subjects is equitable, in relation to the purposes of the research and the setting in which the research will be conducted.

4. Informed consent is obtained in compliance with the IRB policy as outlined in these guidelines.

5. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

6. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

8. All personnel associated with the research that either deal directly with the human subject or with human tissue and/or data and where the project is federally funded, have successfully completed LIU's training program on the protection of human subjects in research.

SECTION 6
APPROVAL PERIODS

IRB approval periods are granted on the basis of degree of risk associated with the particular protocol (but no longer than one year). In the case of full committee reviews, this one-year criterion starts on the date the application receives final approval. Certain projects may require review more often than annually based on other factors aside from

degree of risk. A project approved by the IRB may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve research if the Institutional Review Board has not approved it.

SECTION 7
RESPONSIBILITES OF INVESTIGATORS CONDUCTING IRB APPROVED ACTIVITIES

Once his/her project is approved by the IRB, the investigator(s) must:

1. Conduct every aspect of the project as outlined in the application and as approved by the IRB.

2. Promptly report any revisions or amendments to the research activity for review and approval by the IRB PRIOR to commencement of the revised protocol. (The only exception to this policy is in situations where changes in protocol are required to eliminate apparent, immediate hazards to the subjects).

3. Promptly report any unanticipated problems involving risks to subjects or others.
4. Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials.

5. Where consent/permission/assent form(s) have been approved for the research activity, only IRB approved, stamped forms may be used in the consent process.

The IRB has the authority to suspend, terminate, or place restrictions on any study in which the investigator has not met the above requirements, or in the event where information is disclosed to the IRB that indicates that the rights and/or welfare of human subjects are at risk.

SECTION 8
IRB DISAPPROVAL

Disapproval of an activity may be determined only at meetings of the full committee regardless of the category of review. If the IRB does not approve a research activity, the principal investigator(s) has the right to appeal that decision either in writing or in person at an IRB meeting. If the investigator is not satisfied with the decision subsequently reached by the IRB, s/he may request re-review by the IRB whenever significant changes are made to the research protocol or significant new information becomes available. This re-review requires the submission of a new, updated full application that clearly indicates the changes.

SECTION 9
SUBMISSION FOR TEACHING ACTIVITIES

Participation by students in any teaching activity which involves the potential of more than minimal risk (i.e., more than the risk found in everyday activities) to the student, or is unusual or not necessary to the student's course of study or training in which it occurs, must be accompanied by the student's voluntary, informed consent and must be reviewed and approved by the IRB prior to commencement of the activity.

SECTION 10
RESEARCH INVOLVING MINORS
(IN New York STATE: LESS THAN 18 YEARS OLD)

Minors are considered a vulnerable population and additional protections must be considered in all research activities in which minors are, or may be included.

A. Additional Protections:

1. Obtaining parental permission in most cases. An exception would be if the IRB determines that a research protocol is designed for conditions, or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children.) An appropriate mechanism for protecting the children who will participate must be in place, and the waiver has to be consistent with Federal, state or local law. A waiver of parental permission must also meet the criteria for consent waiver outlined in Section 12.

2. Obtaining minor assent, except where the IRB specifically grants a waiver. In determining whether children are capable of assenting, the IRB must take into account the ages, maturity, and psychological state of the children involved. The IRB may require documentation of assent, such that the minor is presented with an assent form to review and sign.

3. Allowance of participation in only certain categories of research. These categories include:
    a. minimal risk;
    b. more than minimal risk with the possibility of direct benefit;
    c. more than minimal risk without the possibility of direct benefit, but ALL of the following conditions are met:
        1) the risk must represent a minor increase over minimal risk
        2) the research intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in

their actual or expected medical, dental, psychological, social, or educational situations

3) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance to the understanding or amelioration of the subjects' disorder or condition; and
4) the assent of the minor subject and permission from BOTH parents/guardians are solicited in accordance with 45CFR46.

B. Activities that qualify for exemption or expedited review

1. The exempt review and procedures, as outlined in these guidelines, applies to research involving minor subjects with the exception of exemption #2. The exemption for research involving survey or interview procedures or observation of public behavior does not apply to research with minors (17 years of age or younger), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

2. The expedited review and procedures, as outlined in these guidelines, is applicable to research involving minor subjects, as long as the particular activity does not require that the subject be 18 years old or older.

3. The full committee must review all other research involving minors.

SECTION 11
VULNERABLE POPULATIONS: PREGNANT WOMEN, FETUSES, NONVIABLE NEONATES

A. Definitions

1. Fetus – the product of conception from implantation until delivery
2. Neonate – a newborn
3. Viable – being able to survive to the point of independently maintaining heartbeat and respiration
4. Nonviable neonate – a newborn that, although living after delivery, is not viable

B. Pregnant Women or Fetuses

Only the pregnant woman's consent is needed if there is possibility of direct benefit to the pregnant woman OR both the pregnant woman and the fetus, OR no direct benefit to the woman or fetus but the risk to the fetus is minimal (as above).

Both the pregnant woman's and father's (of the fetus) consent is needed if the only potential benefit is to the fetus. Father requirement is waived if he is unavailable, he is incompetent, he is temporarily incapacitated, or the pregnancy is a result of rape or incest.

SECTION 12
GENERAL ISSUES IN INFORMED CONSENT REQUIREMENTS

A. Research Requiring Informed Consent

No investigator may involve a human being as a subject, or use their data or tissue, in research unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative. There are two exceptions to this requirement:

1. Research in which the only involvement of human subjects is that of anonymous observation.

2. The Food and Drug Administration (FDA) permits an exception to the informed consent requirement before the emergency use of a test article, under certain conditions.

B. Waiver of Informed Consent

There are limited conditions under which the Institutional Review Board may waive the requirement for informed consent. An investigator must provide evidence that the following conditions are met:

1. The research involves no more than minimal risk to the subjects.

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

3. The research could not practicably be carried out without the waiver or alteration.

4. Whenever appropriation, the subjects will be provided with additional pertinent information after participation

The Food and Drug Administration permits an exception to the informed consent requirement before the emergency use of a test article under certain conditions.

C. Circumstances Under Which Consent Must Be Sought

Consent must be sought under circumstances where the subject or representative is given enough time to consider whether or not to be in the study and that minimize the possibility of coercion or undue influence. Information provided to the subject or representative must be written in simple language, so all aspects of the research (e.g., purpose, risks, benefits) are clearly stated, and an informed decision may be made.

The IRB encourages researchers to ask potential subjects short questions, after the research has been described and the consent form read, in order to assess that the potential subject has at least a basic understanding of what the research involves. Examples: "Tell me in your own words what this study is all about"; "What do you think will happen to you in this study"; "What do you expect to gain by being in this study"; "What risks might you experience"; "What options do you have if you decide you don't want to be in this study?"

D. Documentation of Informed Consent

Documentation of informed consent is required in most cases. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that:

1. The only record linking the subject to the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. The IRB may determine that each subject be asked whether s/he wants documentation linking the subject with the research, and the subject's wishes will govern; OR

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the requirement of documentation is waived (e.g., use of anonymous survey is proposed), a consent document in the IRB required format must still be used. However, the document is written in letter format ('Dear Subject'), and, rather than requiring the subject's signature to verify consent, the following text is used to end the letter:

'If you _______ (e.g., complete the attached survey, answer these few questions, etc.), it means that you have read (or have had read to you) the information contained in this letter, and would like to be a volunteer in this research study. Thank you, (signatures of investigators)'

E. Consent from Non-English Speaking Subjects

An important part of the consent process is to provide information in a language understandable to the subjects. There are two methods for obtaining consent from non-English speaking subjects.

1. For those consent forms that must be translated into a foreign language, an affidavit of accurate translation must be provided from an appropriate translator who is unaffiliated with the study. The translated consent form and affidavit must be submitted and approved by the IRB before use of the consent form. Or,

2. The Office for Human Research Protection offers guidance on "Obtaining and Documenting Informed Consent of Subjects Who do Not Speak English". This

method involves use of an IRB approved English language consent form, an IRB approved short consent form written in the non-English language, and a witness fluent in both English and the language of the subject. The details are available online at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ic-non-el.htm

F. Capacity to Provide Consent for Research

An essential part of the consent process is assessing whether the potential subject has the capacity to make a decision about participating in a given research study. The proposed subject population and the inherent risks and benefits of a particular study will determine who should be responsible for assessing the capacity of potential subjects. These factors will also determine the procedures that should be followed if the subject is deemed incapable of providing consent. An ethical balance must exist between the need to conduct research that asks questions about certain diseases or disorders, and the need to protect the affected, sometimes vulnerable, subject populations whose inclusion in the study can help answer those questions. However, the rights of the potential subject are always preeminent.

Individuals who lack the capacity to consent for themselves cannot be enrolled in research studies that include more than minimal risk and no direct benefit. These types of studies can enroll individuals who are able to consent for themselves. Any additional safeguards required by the IRB will depend on the nature of the study as well as on the time course (temporary, permanent, progressive or fluctuating) and extent of the alteration in capacity. With increasing risk and decreasing benefit, the safeguards imposed on the study will be necessarily more stringent.

A subject has the capacity to consent to his or her own participation in a research activity if s/he demonstrates an appreciation:

- That the activity is research and not standard treatment;
- Of the risks and benefits of a study;
- Of the alternatives that are available if s/he does not participate;
- That, if s/he chooses not to participate, this decision will be accepted without penalty

G. Who Can Provide Consent if a Subject is Incapable of Doing So

Individuals who may consent on behalf of the subject include:

1. Individuals granted legally documented authority to make decisions specifically regarding participation in research.

2. Family member (in order of priority – spouse, adult child, parent, adult sibling).

3. Individuals named in a health care proxy for research protocols generally recognized in the medical community as offering the optimal treatment choice.

These individuals should receive education about the importance of their role, the study, the health status of the patient, the rights to refuse to participate or to withdraw consent at any time without penalty. This person should be taken through the entire consent process and assent from the subject should be obtained whenever possible.

H. Required Procedures to be followed by Person Obtaining Consent

The individual who signs the consent form as the "person obtaining consent" is responsible for leading the potential subject through the entire consent process. It is the Principal Investigator's responsibility to train and supervise the study personnel who are obtaining consent.

SECTION 13
REQUIRED FORMAT FOR CONSENT FORM: ADULT SUBJECTS (18 YEARS OR OLDER)

All consent forms MUST

- Be printed on LIU letterhead or contain the heading LIU/(Insert Campus)
- Be written at an 8th grade or lower reading level (investigators are encouraged to use computer software applications or other techniques to assess reading level)
- Use a large font (at least 12 point)
- Contain short paragraphs and short, simple and direct sentences
- Define all abbreviations and acronyms when they first appear in text
- Include the mandatory information/sentences/paragraphs shown below.

SAMPLE FOR FACULTY/STAFF/ADMINISTRATORS

LONG ISLAND UNIVERSITY/ *(INSERT CAMPUS NAME)*
Informed Consent Form for Human Research Subjects

You are being asked to volunteer in a research study called *(INSERT TITLE OF PROJECT)*, conducted by *(INVESTIGATOR'S NAME, POSITION, DEPARTMENT)*. The purpose of the research is *(SHOULD BE IN LAYMAN'S LANGUAGE)*.

As a participant, you will be asked to *(DESCRIBE THE PROCEDURES AND TIME INVOLVED, SITE, DATES, POSSIBLE RISKS AND/OR DISCOMFORT.)* Of these procedures, the following are experimental *(IF APPLICABLE, LIST EXPERIMENTAL PROCEDURES*). While there is no direct benefit for your participation in the study, it is reasonable to expect that the results may provide information of value for the field of *(INSERT FIELD)*

Your identity as a participant will remain confidential. Your name will not be included in any forms, questionnaires, etc. This consent form is the only document identifying me as a participant in this study; it will be stored securely in *(IDENTIFY LOCATION)* available only to the investigator *(IF APPLICABLE, LIST OTHERS WHO MAY HAVE ACCESS)*. Data collected will be destroyed at the end of a legally prescribed period of time OR stored for further research. (SPECIFICALLY STATE IF DATA WILL BE KEPT OR IF IT WILL BE DESTROYED) Results will be reported only in the aggregate. *(EXPLAIN OTHERWISE IF THIS IS NOT THE CASE.)* If you are interested in seeing these results, you may contact the principal investigator.

For research involving more than minimal risk, (*INCLUDE SAME INFORMATION DESCRIBED IN SECTION H ABOVE*).

(NOTE: REVIEW ITEMS 1 THROUGH 19 ABOVE FOR ADDITIONAL INFORMATION YOU MAY NEED TO INCLUDE.)

If youhave questions about the research you may contact the investigator, *(NAME, OFFICE PHONE)* or the department chair, *(NAME, OFFICE PHONE)*. If you have questions concerning your rights as a subject, you may contact the Executive Secretary of the Institutional Review Board, Ms. Kathryn Rockett at (516) 299-2523. You may contact *(NAME, TITLE, and PHONE NUMBER)* for answers to any questions you may have in relation to a research-related injury. *(INCLUDE THIS STATEMENT **ONLY** IF YOUR PROJECT HAS ANY RISK OF PHYSICAL INJURY.)*

Your participation in this research is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you am otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

You have fully read the above text and have had the opportunity to ask questions about the purposes and procedures of this study. Your signature acknowledges receipt of a copy of the consent form as well as your willingness to participate.

_____

Typed/Printed Name of Participant

_____ _____

Signature of Participant Date

_____

Typed/Printed Name of Investigator

_____ _____

Signature of Investigator Date

SAMPLE FOR STUDENT PROJECTS

LONG ISLAND UNIVERSITY/ *(INSERT CAMPUS NAME)*
Informed Consent Form for Human Research Subjects

You are being asked to volunteer in a research study called *(INSERT TITLE OF PROJECT),* conducted by *(STUDENT INVESTIGATOR'S NAME, DEPARTMENT)* under the supervision of (*INSERT FACULTY SPONSOR'S NAME, POSITION, DEPARTMENT*). The purpose of the research is *(SHOULD BE IN LAYMAN'S LANGUAGE).*

As a participant, you will be asked to *(DESCRIBE THE PROCEDURES AND TIME INVOLVED, SITE, DATES, POSSIBLE RISKS AND/OR DISCOMFORT.)* While there is no direct benefit to you for participation in the study, it is reasonable to expect that the results may provide information of value for the field of *(INSERT FIELD)*

Your identity as a participant will remain confidential. Your name will not be included in any forms, questionnaires, etc. This consent form is the only document identifying you as a participant in this study; it will be stored securely in *(IDENTIFY LOCATION)* available only to the investigator *(IF APPLICABLE, LIST OTHERS WHO MAY HAVE ACCESS).* Data collected will be destroyed at the end of a legally prescribed period of time OR stored for further research. (SPECIFICALLY STATE IF DATA WILL BE KEPT OR IF IT WILL BE DESTROYED) Results will be reported only in the aggregate. *(EXPLAIN OTHERWISE IF THIS IS NOT THE CASE.)* If you are interested in seeing these results, you may contact the principal investigator.

For research involving more than minimal risk, (*INCLUDE SAME INFORMATION DESCRIBED IN SECTION H ABOVE*).

(NOTE: REVIEW ITEMS 1 THROUGH 19 ABOVE FOR ADDITIONAL

INFORMATION YOU MAY NEED TO INCLUDE.)

If you have questions about the research you may contact the investigator, *(NAME, OFFICE PHONE)* or the faculty sponsor, *(NAME, OFFICE PHONE)*. If you have questions concerning my rights as a subject, you may contact the Executive Secretary of the Institutional Review Board, Ms. Kathryn Rockett at (516) 299-2523. You may contact *(NAME, TITLE, and PHONE NUMBER)* for answers to any questions you may have in relation to a research-related injury. *(INCLUDE THIS STATEMENT **ONLY** IF YOUR PROJECT HAS ANY RISK OF PHYSICAL INJURY.)*

Your participation in this research is voluntary. Refusal to participate or discontinue participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled

Your signature indicates you have fully read the above text and have had the opportunity to ask questions about the purposes and procedures of this study. Your signature also acknowledges receipt of a copy of the consent form as well as your willingness to participate.

_____

Typed/Printed Name of Participant

_____ _____

Signature of Participant Date

_____

Typed/Printed Name of Investigator

_____ _____

Signature of Investigator Date

SECTION 14
CONSENT/PERMISSION/ASSENT REQUIREMENTS: MINOR SUBJECTS (LESS THAN 18 YEARS OLD)

All consent forms MUST

- Be printed on LIU letterhead or contain the heading LIU/(Insert Campus)
- Be written at an 8th grade or lower reading level (investigators are encouraged to use computer software applications or other techniques to assess reading level)
- Use a large font (at least 12 point)
- Contain short paragraphs and short, simple and direct sentences
- Define all abbreviations and acronyms when they first appear in text
- Include the mandatory information/sentences/paragraphs shown below.

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ASSENT (AND DOCUMENTATION OF ASSENT) REQUIREMENT

The IRB requires that provisions be made for obtaining the assent of children to be subjects in certain research activities. Aside from age (usually 11-17 years old), the maturity and psychological/physical state is taken into account in determining the ability of obtaining assent. The IRB may require submission of an assent document which states, in very simple, general terms, the purpose of the study, what is expected of the child, the risks, benefits, the right to leave the study at any time, and who the child can talk to (parent and/or investigator) if s/he has questions about the study. Following is an example of an Assent Form: (Note: Information in italics is presented for explanation and example only. This information should be changed to fit each project.)

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LONG ISLAND UNIVERSITY/ (INSERT CAMPUS NAME)
Assent Form for Human Research Subjects

Title:

Principal Investigator:
Faculty Advisor (if applicable):

Why are you here?
The researchers (that's us) want to tell you about a study looking at how…. We want to…. We decided to invite you to be in the study because we want to learn more about….and because your parent or guardian thought you might like to be in the study too.

Why is this study being done?
We want to learn more about….

What will happen to me?
Only if you want, these things will happen:

1) Answer questions about…. 2) Play with toys while we watch you….

Will the study help me?

What if I have questions?
You can ask us questions any time. You can ask questions now or later. You can talk to any of the people who are helping with the study.

Do my parents know about this?
This study was explained to your parents and they said that you could be in it. You can talk this over with them before you decide.

Do I have to be in the study?
You do not have to be in the study. No one will be upset if you don't want to do this. If you don't want to be in this study, you just have to tell us. If you want to be in the study, you just have to tell us. You can say yes now and change your mind later. It's up to you.

Writing your name on this page means that the page was read by you or to you and that you agree to be in the study. You know what will happen to you. If you decide to quit the study all you have to do is to tell the person in charge,

_____	_____
MY NAME	TODAY'S DATE
_____	_____
INVESTIGATOR'S SIGNATURE	DATE

SECTION 15
CONTINUED REVIEW OF IRB-APPROVED ACTIVITIES

A. Observation of Research by IRB

The IRB has the authority to inspect records, and to observe (or have a third party observe) the consent process and the research of any activity that it approves.

B. Renewal Procedures

As detailed in Section 6, the IRB approval periods are granted on the basis of degree of risk associated with the particular protocol (but no greater than 1 year). **It is the Principal Investigator's responsibility to maintain continued approval for his or her study. However, the Office of Sponsored Research sends reminder notices as outlined below.**

1. Renewal Notices
    a. Approximately 3 months prior to the end of the approval period, investigators should prepare and send their renewal materials to the Secretary of the IRB in the Office of Sponsored Research.
    b. Projects are automatically inactivated if the renewal materials are not received by the end of the month in which their approval expires. The IRB requires that all activities involving human subjects that were covered under the originally approved protocol be stopped immediately. The Assistant Director must be contacted if and when the investigator wishes to reactivate the study.

2. Required renewal materials include:
    a. Renewal application, requiring completion, followed by signatures of the investigator, chair of the department and in the case of undergraduate or graduate student investigators, signature of the student's advisor.
    b. Progress report, which is a summary of the human subjects aspects of the project over the past year, including number of subjects run, adverse consequences, new information, results of research, resulting publications, etc.
    c. Consent/Permission/Assent Forms to be used for the upcoming approval period.

C. Amendments, Adverse Events

All amendments to approved protocols must be submitted to the IRB for review and approval prior to commencement of the revised study or use of a revised consent/permission/assent form. Adverse events that occur on-site will be reviewed by the full committee at a convened meeting. Those occurring at another center conducting the study (i.e., in the case of multi-center studies) will be reviewed in a timely manner.

Changes to consent/permission/assent forms that are required as a result of an amended protocol, or subsequent to review of adverse events (i.e., addition to the risks section of the consent form), should be made to the most current IRB-approved version. The

revised version would be used to consent new subjects for enrollment in the study. However, in order to inform subjects who are already enrolled in the study of the changes to the study, the following format should be used. If the study involves minors, an additional addendum directed to the parent, as well as a revised assent form, should be drafted as well. (Note: Information in italics is presented for explanation or example only; this information should be changed to fit each project.)

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Departmental Letterhead

Project title:
Investigators:

Addendum to Consent Form

You have already agreed to be a volunteer in the research study referenced above.

In the consent form you signed (attached), you were informed that you would be told of any new information that might affect your willingness to continue in this study.

This addendum serves to tell you that … (*e.g., your participation will be extended another 3 weeks … OR … An additional questionnaire will be given to you to complete … OR … An additional 3 tsp. of blood will be taken at your 4th visit … etc. If applicable, explain why the change is being implemented, and provide details regarding relevant changes to risks, benefits, alternative treatments, etc. that occur as a result of the revised protocol.)*

You are reminded that:

- All other information from the original consent form remains unchanged.
- Your participation in this study continues to be voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a copy of this consent addendum to keep.
- You do not waive any of your legal rights by signing this consent form.

If you have any questions about this study, you may contact *[insert investigator's name and telephone number]*. If you have any questions about

your rights as a research subject, you may contact Ms. Kathryn S. Rockett, Executive Secretary, Institutional Review Board, 516-299-2523.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to continue to be a volunteer in this study.

_____

Subject Name

_____

Subject Signature Date

_____

Signature of Person Obtaining Consent Date

A serious event, other than death or a life threatening event, is one that results in inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity; a congenital anomaly;/birth defect. It is also defined as a significant medical event that requires medical or surgical intervention to prevent death, a life-threatening event, or one of the other outcomes listed above. Reasonable judgment must be used to determine what constitutes a serious event. Such events do not have to be physical in nature; attention must be paid to psychological harm and threats to privacy or subject safety.

ALL adverse events must be reported to the IRB within 1 – 5 working days as per the following chart.

	Death/Life Threatening	**Other Serious (not life threatening)**	**Non-Serious**
Expected	Report to IRB within 5 working days of occurrence	Report to IRB at time of continuing review	No report required
Unexpected	Report to IRB within 1 working day of occurrence	Report to IRB within 5 working days of occurrence	Report to IRB at time of continuing review

Expected – event is identified by nature, severity or frequency in the risks section of the consent form
Unexpected – event is not identified by nature, severity or frequency in the risks section of the consent form

Each report of an adverse event must be signed by the Principal Investigator or Faculty Supervisor (not student investigator). The Investigator will be expected to provide a summary and assessment of the event. The report will be forwarded immediately to the appropriate IRB Chair for review and course of action. The Executive Secretary will

inform the Institutional Official of all reports of adverse events. The Institutional Official will promptly notify federal sponsors of problems as required under 45CFR46.103(b)(5); OHRP will be notified where appropriate.

SECTION 16
EXEMPTIONS FROM IRB PRIOR APPROVAL REQUIREMENT

The only activity that is exempt from prior review and approval from the IRB involves the emergency use of an investigational drug (i.e., not approved by the Food and Drug Administration). Emergency use is defined as the use of a test article on a human subject in a life-threatening situation in which there is no standard acceptable treatment available and in which there is not sufficient time to obtain IRB approval.

The emergency use must be reported to the IRB within 5 working days and should include:

1. Patient history
2. Justification for the emergency use
3. Department chair endorsement
4. Consent form
5. Investigational drug brochure and/or protocol (generally available from the pharmaceutical company.

Any subsequent use of the investigational drug (i.e., use in another patient) must be approved by the IRB via the standard application process prior to commencement of the activity.

The investigator is required to obtain informed consent of the subject or the legally authorized representative unless both the investigator and another independent physician certified in writing all of the following:

1. The human subject is confronted by a life-threatening situation necessitating the use of the test article,

2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject,

3. Time is not sufficient to obtain consent from the subject's legal representative, AND

4. No alternative method of approved or generally recognized therapy is available that provides and equal or greater likelihood of saving the life of the subject.

If time is not sufficient to obtain an independent physician's determination that the above four conditions apply, the investigator shall make the determination and, within 5 working days after the use of the drug, have the determination reviewed and evaluated in writing by such a physician. Notification to the IRB is still required within the 5 working days.

SECTION 17
IRB RECORDS

The Executive Secretary of the Institutional Review Board maintains the following IRB records:

1. Current list of IRB members, qualifications, resumes.

2. Minutes of meetings, including information regarding member attendance, discussions held, decisions made, and voting results.

3. All materials submitted to the committee for initial and continued review of each study including: IRB applications, protocol, submitted and final consent forms, adverse reaction reports, proposed amendments, progress reports, and, where applicable, sponsoring agencies' requirements. This information is retained for a minimum period of three years following the inactivation of a project.

SECTION 18
VIOLATIONS OF IRB POLICY

The IRB has the authority to suspend, terminate, or place restrictions on any study in which the investigator has not met the policy or procedural requirements addressed in this handbook, and/or in the event where information is disclosed to the Office of Sponsored Research and/or IRB that indicates that the rights and/or welfare of human subjects are at risk.

Reports of violations of this policy will be brought before the IRB at a convened meeting. The IRB will make a determination regarding the need for additional information, or further investigation. The affected Departmental Chair and Dean and the Vice President for Academic Affairs will be copied on all correspondence between the committee and the involved party(ies). Upon determination that a violation of this policy has occurred, the IRB may, for example, require that the activity in question be halted until such time that corrective action is taken. If the IRB determines that the violation involves possible scholarly or scientific misconduct, the Vice President for Academic Affairs will be notified, through the Executive Secretary, and appropriate action will be taken in accordance with established University assurances, policies, and procedures.

In situations where subject safety is involved, and/or the violations are apparent, the Chair of the IRB, in consultation with other IRB members and/or administrators as appropriate, may take immediate action (e.g., suspend the activities in question) prior to review by the full committee.

In accordance with LIU's Federal Wide Assurance, the following violations will be reported to the Vice President for Academic Affairs, OHRP, FDA, and affected sponsor(s) where applicable:

1. Any unanticipated problems involving risks to subjects or others.

2. Any serious or continuing noncompliance with 45CFR46 or the determinations of the IRB.

3. Any suspension or termination of IRB approval.

If the IRB determines that the violation involves possible scholarly or scientific misconduct, the Vice President for Academic Affairs will be notified and appropriate action will be taken in accordance with established University assurances, policies, and procedures.

All reports/allegations regarding human subject research activities made to the Office of Sponsored Research and/or the IRB will be held confidential, to the extent allowed by law.

SECTION 19
TRAINING OF INVESTIGATORS IN THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH ACTIVITIES

All individuals who are involved in human subjects research, who will work directly with subjects or with data or biological specimens derived from subjects or patients, and who has external funding from a federal agency, are required to be trained in the protection of human subjects in research activities. If all such individuals are not trained, work on on-going projects must be suspended. Training must be verified by the Office of Sponsored Research.

This requirement may be met by the successful completion of a seminar coordinated through the Office of Sponsored Research. The seminar is available to LIU faculty, staff, and students.

SECTION 20
CONFLICT OF INTEREST / FINANCIAL DISCLOSURE

An institution conducting research that is sponsored by a pharmaceutical company is usually paid in accordance with the reasonable costs of conducting the study. This may include being paid on a 'per enrolled subject' basis. These funds may be used to support research work in the investigator's laboratory. This, in and of itself does not constitute a conflict of interest, but the subject has the right to disclosure of this relationship. A section should be added to the informed consent document as follows:

> This project is funded, in part, by a grant or contract from *(insert name of pharmaceutical company)* to Long Island University, in support of the investigator's work on this study.

There are provisions in some contracts for 'enrollment incentives' (also referred to as 'competitive enrollment'). This refers to the situation where the institution will be paid more by the sponsor if a certain quote is met. This method of compensation raises ethical concerns, and constitutes an area of debate within the field of Human Subjects research. For example, the December 2001 report of the Association of Medical College's (AAMC) Task Force on Financial conflicts on interest in Clinical Research states:

"Payments for subject enrollment…should be permitted on to the extent such payments:

- Are reasonably related to costs incurred, as specified in the research agreement between the sponsor and the institution
- Reflect the fair market value of services performed, and
- Are commensurate with the efforts of the individuals performing the research."

Such incentives may also serve to keep the investigator aware of the need for eligible subjects. It is advantageous for research on the etiology, prevention and treatment of diseases to be conducted as quickly as possible, so that results can be assessed, and future research planned. Protocols involving enrollment incentives will be assessed by the Office of Sponsored Research and the IRB on a case by case basis.

The IRB retains the right to refuse to allow enrollment incentives for a particular protocol. Further, enrollment incentives (monetary or otherwise) meant to provide personnel benefit to any investigator are prohibited.

SECTION 21
Additional Important Definitions

Intervention includes both physical procedures by data are gathered and manipulations of the subject or subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subjects.

Private information includes information about behavior that occurs in context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual can reasonable to expect will not be made public.

Privacy refers to persons and their interest in controlling access to themselves.

Confidentiality refers to agreements with the subject about how the data will be handled.