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FOREWORD

SUNY Delhi is guided by the ethical principles regarding all research involving humans as subjects set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "Belmont Report").

While the primary responsibility for protecting the rights and welfare of human subjects rests with each individual who initiates, directs, or engages in research, it is the responsibility of SUNY Delhi to reasonably ensure that the human subjects, in research conducted under its auspices, are adequately protected. Faculty members are responsible for ensuring that their students are made aware of these requirements.

SUNY Delhi has established an Institutional Review Board (IRB), which is responsible for meeting the institution's obligations to review research involving human subjects. All research projects involving human subjects conducted by SUNY Delhi faculty, staff and students, or conducted under the sponsorship or auspices of the institution, must be reviewed and approved by the IRB. This includes research involving subjects from outside the college, as well as research not funded by outside sources. The IRB has been established in compliance with the U.S. Code of Federal Regulations, Title 45 Part 46, Office of Human Research Protection (OHRP) at the Department of Health and Human Services (DHHS), and has the responsibility and authority to review, approve, disapprove, or require changes in research activities involving human subjects.

Research Conducted by Non-SUNY Delhi Investigators

At SUNY Delhi, the IRB requires any non-SUNY-Delhi investigators to have a sponsor on campus that is willing to serve as a facilitator for the research. In addition, the IRB requires a copy of the approved IRB protocol from the originating institution of the guest investigator before it will approve the research on SUNY Delhi’s campus. The IRB application and approval letter shall be forwarded to the SUNY Delhi sponsor for review and submission to SUNY Delhi’s IRB. This procedure assures that the research approved adheres to SUNY Delhi’s IRB policies. The guest investigator will receive written authorization from the IRB Chair granting approval to conduct the research.

OVERSIGHT AND ADMINISTRATION

The Institutional Official overseeing the activities of the Institutional Review Board is the College Provost.

Committee Membership

In compliance with DHHS regulations, the IRB Committee at SUNY Delhi is comprised of people from diverse backgrounds and with professional competence necessary to review specific research activities. A variety of professions are represented, and the Committee includes at least one member whose primary expertise is in a nonscientific area, as well as one member who is not otherwise affiliated with the institution, either primarily or through an immediate family member. The IRB Committee must be sufficiently qualified through the experience, expertise, and diversity of its members, including race, gender, cultural background and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel. Representatives from the SUNY Delhi Institutional Research and Grants Offices serve ex officio on the SUNY Delhi IRB Committee, are considered non-voting members, and are as such not considered part of the committee’s quorum. A
quorum is defined to be more than 50% of the voting members.

The Chair of the IRB is appointed by the College Provost for a three (3)-academic-year term, with responsibilities to be rotated to committee members. IRB members are appointed with unlimited reappointments of three (3) years by the College Provost with approval of the College President. When members are replaced, the replacement will finish the term of the member they are replacing, then begin their three-year term. Note taking responsibilities will be rotated from meeting to meeting.

Conflicts of Interest
The IRB Committee shall have no member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Any IRB member must disclose conflicting interest in a proposal. This member cannot serve as a reviewer of the proposal and must leave the room during discussion and voting, except if the IRB member is providing information at the IRB’s request.

A conflict of interest exists if any of the following occur:

- IRB member is listed as an investigator or is a member of the research team;
- IRB member is a professional supervisor of an investigator;
- IRB member is a family member or has a close personal relationship with an investigator;
- Any other reason for which the IRB member believes he or she has a conflicting interest in the research proposal.

If an IRB member becomes aware of a conflict of interest, the member needs to immediately identify the conflict to the committee. The minutes of any meeting in which conflicting interests are discussed and/or voted on will document the recusal of the IRB member.

OPERATIONS

Training Requirements
Members of the IRB Committee must receive certification by completing the IRB’s online training module, hosted on the SUNY Delhi Learning Management System (i.e. Blackboard, Moodle, WebCT, etc.), and receive a score of 70% or greater on the accompanying quiz. Certification certificates for IRB Committee members are valid for one (1) year from the date of the completed quiz.

All faculty and staff members planning to conduct research activities must first receive certification from the IRB. To receive certification, researchers must complete the IRB’s online training module, hosted on the SUNY Delhi Learning Management System, and receive a score of 70% or greater on the accompanying quiz. Once completed, the researcher will receive a certification letter from the IRB. Certification certificates are valid for three (3) years from the date of the completed quiz.

Review Procedures
Requests for IRB review must be submitted at least three (3) weeks prior to the next scheduled IRB meeting (schedule posted on the IRB website as available; if there is no schedule, contact the IRB chairperson). In order for the IRB to have adequate information on which to base their review of a proposed project, the investigator submitting a proposal must attach a written description of the project, referred to herein as a “protocol.”
**Step 1 – Protocol Submission**
The Principal Investigator should complete the Request for IRB Review form and the IRB and Primary Investigator Checklist and submit both to the IRB chair via email. The written description of the project must at a minimum specify the following:

1. The purpose and significance of the project, including a statement of hypotheses to be tested, along with an indication of the theoretical, biomedical and/or social significance of potential findings.
2. A description of the population of human subjects that will be used, and a description of the procedures that will be used for recruiting subjects, for obtaining informed consent (a copy of the proposed informed consent form must be attached), for assuring the confidentiality of subjects’ data, and for debriefing them upon conclusion of the project.
3. A description of the materials to which subjects will be exposed during the course of the study, procedures for conducting the study, and a description of the independent and dependent variables under study.
4. Assurance that the Principal Investigator will take all necessary steps to protect the safety and security of data collected, along with a description of those steps.

The form should carry the signature of the Principal Investigator’s supervisor.

**Step 2 – Review by Chair and Designee**
Under federal rules, certain research proposals may not require review by the convened IRB Committee, and may be reviewed by the Chair and one or more experienced reviewers designated by the Chair through the expedited review process. The Chair reviews all applications upon submission, and, with assistance from an IRB designee, makes an institutional determination within two weeks of receipt whether the research protocols qualify for: 1. exemption from review; 2. expedited review; or 3. full IRB review. If exempt, the Chair will work with at least one other committee member to evaluate the proposal and confirm that determination. If the determination is disputed, the proposal is presented to the full committee. At this point in the review, the researcher may be asked to make revisions in the protocol to make it acceptable. The full committee will be informed of the determination.

**Step 3 – IRB Review**
If investigation results in a determination that the protocol needs review by the full committee, the request will be evaluated at the next scheduled IRB meeting. The IRB makes decisions based on the following requirements:

1. Risks to participants are minimized;
2. Risks to participants are reasonable in relation to anticipated benefits and knowledge that may be expected to result;
3. Recruitment of participants is equitable and free of coercion;
4. Informed consent will be obtained from each participant or his/her representative;
5. Informed consent will be appropriately documented;
6. Collected data will be monitored to ensure the safety of participants; and
7. Privacy of participants and confidentiality of data is maintained.

Informed consent means the knowing consent of an individual, or his or her legally authorized
representative, who is able to exercise free power of choice without undue inducement or any form of force, fraud, deceit, duress, or other form of constraint or coercion. Please see the section of this document entitled “Informed Consent” for additional information.

Please see the section of this document entitled “review” for additional information on the three types of IRB review. For more detailed explanation of IRB review standards for approval, please see 45 CFR 46.111.

**Step 4 – IRB Action**
Except when an expedited review procedure is used, the IRB will review proposed research at convened monthly meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. To facilitate the review of research and the protection of the rights and welfare of human participants, research investigators and department heads are encouraged to attend IRB meetings when invited.

**IRB Decisions**
The full IRB may act on a protocol in one of four ways:

1. The protocol may be approved;  
2. The protocol may be approved pending modifications (the modified protocol may or may not need to be re-reviewed by the full IRB);  
3. The protocol may be deferred, needing substantial revisions or clarifications (such protocols always need to be re-reviewed by the full IRB);  
4. The protocol may be disapproved (in this case, the study may be re-written to address all concerns, and re-submitted for full IRB review).

**Notification of Principal Investigator**
Written notification of actions taken at the IRB meeting will be mailed to the Principal Investigator within one (1) week of the meeting. Attached to the standard approval letter is the final approved version of the consent form, with the IRB approval and expiration date affixed to each page. The stamped consent may be copied but must not be changed in any way. The consent form is valid until the expiration date one year later. If a consent form is revised and approved by the IRB during this period, it is stamped with IRB approval, the expiration date, and the date of the revision. The expiration date remains the same as it was prior to the change.

In cases where a study is disapproved, the IRB will provide its rationale for the action taken. The Principal Investigator may request an appearance before the IRB to present arguments for reversal of the decision or propose a change in the protocol based on the advice and counsel of the IRB. Decisions of the IRB committee shall be considered final.

Once a project is approved, no protocol or consent form changes, amendments, or addenda may be made without prior IRB review and approval. Please refer to the section of this document entitled “IRB Enforcement and Monitoring” for additional information.

All publicity (advertisements, flyers, etc.) regarding approved research protocols must note approval by the IRB Committee.
REVIEW

Exempt

According to regulations, certain human subjects research activities may be eligible for a determination of exempt status by the Committee. Research may be considered for exempt status if the only involvement of human subjects in the research falls into 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. 45 C.F.R. § 46.101(b)(1);

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. 45 C.F.R. § 46.101(b)(2);

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not otherwise exempt if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. 45 C.F.R. § 46.101(b)(3);

4. 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. 45 C.F.R. § 46.101(b)(4);

5. 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. 45 C.F.R. § 46.101(b)(5);

6. 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 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. 45 C.F.R. § 46.101(b)(6);

Certain research which is exempt for adult subjects is not exempt when children are involved. The Committee, not the investigator, must make the determination that research is exempt under the Common Rule. This determination can be made either by the IRB Committee Chair or by a designated voting committee member.
Expedited
Under federal rules, certain research proposals may not require review by a convened Committee, and may be reviewed by the Chair and another committee member designated by the Chair. Categories of research eligible for expedited review are set forth fully in the Federal Register at 63 Fed. Reg. 60364-60367 (November 9, 1998). The expedited review process may be appropriate for research which: 1. involves no more than minimal risk to the subject, meaning that "the probability 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 (45 CFR 46.102 (i))” and 2. involves human subjects in the research only in one of the following categories:

1. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis);
2. Collection of data from voice, video, digital, or image recordings made for research purposes;
3. 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;
4. Collection of biological specimens for research purposes by noninvasive means (e.g., skin cells collected by scraping or swab, hair and nail clippings, saliva samples);
5. Moderate exercise by healthy volunteers; and/or moderate exercise with minor stimulants such as caffeine;
6. Muscular strength training, body composition assessment, measurements of weight and height of healthy volunteers;
7. Research involving the use of educational tests or materials (data, documents, or records) if information taken from these sources is recorded in such a manner that participants can be identified (assuming minimal risk);
8. Minor changes in previously approved research (i.e., changes that do not affect risk or benefit);
9. Continuations of approval for previously approved no-risk research with no more than minor changes in procedures;
10. Any other category specifically added to this list by HHS and published in the Federal Register.

Full
Projects that do not meet criteria for Exemption or Expedited Review must go through a Full Review. Research projects requiring full IRB review include:

1. Projects in which subjects will be exposed to more than minimal risk
2. Projects requiring the use of deception
3. Interviews or surveys on sensitive topics (e.g., sexual activity, alcohol or drug use, illegal behavior)
4. Projects involving psychological or physiological intervention or non-curricular, interactive research in schools
5. Projects in which there is a risk to the participants’ confidentiality
6. Projects requiring the use of subjects from populations in need of special protection (e.g., prisoners, individuals with disabilities, pregnant women, and children).

7. Research conducted outside of the US.

8. Any other category specifically added to this list by HHS and published in the Federal Register.

When conducting a full review of a research project, the IRB must be assured that:

1. The risks to participants have been minimized;
2. The risks to the participants are reasonable in relation to anticipated benefits;
3. Selection of participants is equitable;
4. Informed consent is sought;
5. Informed consent will be appropriately documented;
6. Data collection will be monitored to ensure the participants’ safety;
7. The privacy of the participants will be protected and the confidentiality of the data maintained;
8. Appropriate debriefing is conducted.

The IRB must also be assured that when participants are likely to be vulnerable to coercion or undue influence (as in the case of children), additional safeguards have been included to protect the rights and welfare of these participants.

INFORMED CONSENT

No person who has the capacity for consent may be enrolled in a study without his or her informed consent. An investigator shall seek consent under the following circumstances:

1. Sufficient opportunity is provided to the prospective subject, or his or her representative, to consider whether or not to participate;
2. The possibility of coercion or undue influence is minimized;
3. The information that is given to the prospective subject, or his or her representative, shall be in language understandable to the subject or representative; and
4. The subject, or his or her representative, cannot be made to waive or appear to waive any of his or her legal rights, or release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

All consent forms must include explicit information about the study for which the participant can make an informed decision, including contact information for both the Principal Investigator and the SUNY Delhi Institutional Review Board. A copy of the completed form must be provided to the consenting subject. Any subject may withdraw from any research to which they have consented at any time, without giving a reason, and without penalty.

If applying for a Certificate of Confidentiality through NIH, the principal investigator must add language to the consent form indicating that the certificate is in effect. The IRB may approve the proposal conditionally, pending investigator's receipt of the certificate.

All research in schools requires written permission of the school district, normally the
superintendent or his/her designee. Written parental permission is required for all research on minors, unless it involves non-interactive observation of normal classroom activity. Any material changes to approved research protocols require the re-consent of all subjects.

**Waivers of / Divergence from Signed Consent Requirement**

The SUNY Delhi IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the SUNY Delhi IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects (i.e., phone surveys);
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 (i.e., internet research); and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

For survey projects, informed consent is obtained by providing a detailed explanation of the purpose and protocol for the research project to the potential subject/respondent. The completion of the survey instrument (i.e. questionnaire/interview) shall constitute informed consent.
SPECIAL POPULATIONS

Federal regulations require that special consideration be given to protecting the welfare of particularly vulnerable participants, such as children, prisoners, pregnant women, decisionally impaired persons, and others. When research is reviewed involving a category of vulnerable participants, the IRB shall include in its reviewing body one or more individuals who have as a primary concern the welfare of these participants. In studies involving review by multiple IRBs, only one of the IRBs must include such an individual. In general, regulations allow approval of research that is of minimal risk or that will benefit the subjects directly. The regulations also require special safeguards, particularly with respect to informed consent, as follows.

Children
The most common special population in research is children. Studies involving children are more strictly regulated than studies involving adults. Where children are human subjects, the proposal must provide for obtaining the consent of the legal representative of the child (parent or guardian) and the assent of the child.

Research which does not involve direct intervention with students or which uses non-identifiable results of educational tests would fall in the category of research which would be exempt from federal or state regulations. Such research is not exempt, however, from review by the IRB.

Prisoners
Studies involving prisoners as subjects raise special issues. "Prisoner" is defined to include any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Decisionally Impaired
Where research is conducted using human subjects who suffer from mental disorders that may affect their decision making capacity, additional protections are needed. Examples of such disorders include mental retardation and significant psychiatric disorders.

Pregnant Women or Fetuses
Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. Any risk is the least possible for achieving the objectives of the research.

Women And Minorities In Research
All research involving human subjects should be designed and conducted to include members of both genders and members of minority groups, unless a clear and compelling rationale and justification establishes that such inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Cost is not an acceptable reason for the exclusion of persons of one gender or persons who are members of a minority group, except when such study would duplicate data from other sources.

Studies should employ a design with gender, racial and/or age representations appropriate to the
known incidence/prevalence of the disease or condition being studied. If subjects of a certain gender, race, or age group are to be excluded, such exclusion must be clearly explained and justified by the investigator. It is not expected that every minority group and subpopulation will be included in each study. However, broad representation and diversity are the goals, even if multiple clinics and sites are needed to accomplish it.

SPECIAL TYPES OF RESEARCH PROJECTS

Course Assignments
Campus activities using human subjects (including individuals outside the classroom setting) do not require review if the purpose is pedagogical and the results are used only within the campus community.

Survey research conducted as a class assignment for a specific course does not require IRB approval when responses of participants are not identifiable by name or description, and the responses pertain to non-sensitive topics. Responses that are identifiable or seek participant behavior responses about sensitive topics must follow normal IRB review protocol. Sensitive topics include but are not limited to sexual attitudes, sexual practices, information relating to the use of alcohol and other substances, information pertaining to illegal conduct, information that could be harmful to the participant, and information that would normally be recorded in a patient’s medical record (including information relating to mental health).

Anonymous classroom assessment for improvement of classroom instruction does not require IRB review. Instructors should gain approval from department chair or dean when student research will be conducted as part of a course.

If activities clearly meet these characteristics IRB review is not required. If the results have the potential for public dissemination off campus, IRB approval must be obtained. If the instructor/investigator is not sure whether activities should be reviewed or not, a proposal should be submitted for IRB review.

Classroom Research Using Undergraduate Students as Human Subjects
Certain courses may involve their students in in-class experiments. These experimental activities require consent from the student participants, or their parents if the student is under 18, and it is further required that the experiments themselves be reviewed by the IRB. For courses that either requires or allow students to volunteer in research projects for credit (not related to in-class educational experiences), the IRB recommends the following protective steps:

1. The instructor should have a clear statement in the course syllabus about whether participation in the classroom research is voluntary and/or how their participation is related to the goals/objectives of the course or how it might influence their grade.
2. The instructor should be mindful of the types of situations which may occur if the student is uncomfortable with participating and provide the students with reasonable alternatives which would fulfill the requirement/credit if they are uncomfortable with participation. The alternatives should be neither more onerous nor time-consuming than participation
3. The instructor, whenever possible, should avoid circumstances in which participants may feel coerced or unduly influenced to participate.

Student-Conducted Investigations
In some instances, students may conduct research using human subjects. In such instances, all student investigators must have a SUNY Delhi faculty or staff supervisor. If the research is being conducted as part of a course, the protection of research participants should be discussed in class as part of the educational process in preparation for the investigations. Student research projects must involve no more than minimal risk to participants. In addition, the supervisor is responsible for the following:

1. Ensuring that the student has received the appropriate training to minimize the risks to participants and attesting that the student has read and understood the ethical principles of respect for persons, beneficence, and justice as described in the Belmont Report;
2. Assuring that all IRB provisions are complied with by the student investigator(s). These provisions include, but are not limited to, submitting the protocol in sufficient time to the IRB for review, proper training for obtaining consent and maintaining confidentiality, adhering to the procedures outlined in the approved protocol, notifying the IRB of any changes to the protocol, and submitting a final report to the IRB upon completion of the study;
3. Insuring that every effort be made to minimize the risk of invasion of personal privacy and to maintain confidentiality. Identifiers linking the data to the respondent should not be collected unless necessary to the study. If such information is collected, the faculty member should provide guidance to the student on methods of safeguarding confidentiality;
4. Insuring that topics of a sensitive nature are avoided by student researchers who are not sufficiently experienced in such research.

International Research Projects
Research projects conducted internationally require adherence to local as well as US laws. Investigators must provide the Committee with documentation of local IRB approval or justification of why local IRB approval cannot be obtained.

Internet Research
Research on the Internet presents new concerns to the prevalent human participants issues: risk, consent, participation by minors, and confidentiality. Breach of confidentiality is the primary source of harm in most Internet research and some sensitive research may not be appropriate for the Internet due to this potential risk. Please note that informed consent must still be obtained. One acceptable method for obtaining consent is to include all required informed consent information within the introduction to of the study, and then placing the following statement: “Completion of this survey indicates that you understand the information provided above and you consent to participate in this research project.”

Consent
The IRB can waive the requirement for signed consent when appropriate. Innocuous research on non-sensitive topics conducted over the Internet may not need documentation of consent (NOTE: only the IRB can make that decision). As it is may be difficult to get a signed consent form over the Internet, where signature is required, investigators must indicate to the IRB how they plan to obtain consent from participants.
Participation by minors
The IRB has the authority to waive the requirement for parental permission and where the research qualifies for such a waiver, no additional safeguards for minors are required. Where parental permission is required, investigators can use passwords as above. Because no system can guarantee that minors are not participating, some research may not be appropriate for the Internet.

Confidentiality
Investigators need to address how they intend to assure confidentiality, keeping in mind that the degree of concern over confidentiality is directly related to the sensitivity of the data. When a research project is conducted over the Internet, the following statement must be placed in the introduction of the study: Please note that absolute confidentiality cannot be guaranteed due to the limited protections of Internet access.

IRB ENFORCEMENT AND MONITORING

Review of Serious Adverse Events and/or Unanticipated Problems
Investigators are required to report serious adverse events and/or unanticipated problems related to the protocol to the IRB within five (5) working days, using the Adverse Event Report form. The IRB may elect to mandate a shorter time period for reporting serious adverse events and/or unanticipated problems to the IRB. A serious adverse event is defined as any event that suggests a significant hazard, contraindication, side effect, or precaution. An unanticipated problem is any adverse event that is not identified in severity or specificity in the consent form, or protocol.

Adverse event reports are reviewed by the Chair or designee. Upon receipt of a report of an adverse event, the Chair or designee will decide if urgent action is necessary to eliminate apparent immediate hazards to the human subjects. Such findings may include:

1. Changes to the protocol are needed to minimize risks to subjects;
2. Changes to the consent form are needed to accurately reflect the nature, frequency or severity of the event;
3. Subjects should be asked to re-consent to study participation;
4. The study should be placed on temporary hold to new enrollment and/or the study procedures should be discontinued because, based on the information available, the risk benefit ratio appears to be unfavorable to the subjects.

The Chair will establish procedures to discuss reports of significant adverse event reports (and actions taken by the Chair or designee upon receipt of the Adverse Event Report) at the next convened IRB meeting. The IRB shall determine appropriate action in response to the report including one or more of the following:

1. Deciding that no further action is necessary (the research may continue);
2. Requiring further investigation by a member or outside expert designated by the Chair prior to the next meeting of the Committee;
3. Requiring that additional information regarding risks be given to subjects;
4. Suspending approval; or
5. Terminating approval.
The investigator shall receive written notice of any action taken by the IRB and the reasons for that action within five (5) working days of the IRB’s decision to take action. The IRB is required to record in the minutes “any serious adverse events and/or unanticipated problems involving risks to subjects or others.” If the research protocol is suspended or terminated, additional notice shall be provided.

**Protocol Modifications**

As the research study proceeds, it is recognized that modifications to research protocols and informed consent forms may be required. Any proposed modification to an IRB approved research protocol or informed consent form must be approved by the IRB prior to implementation. Investigators are required to report modifications from approved protocols and consent forms to the IRB, by resubmitting the most recently approved review form with changes in a bolded font.

The category of review (i.e. expedited or full) of the proposed modification to an approved research protocol or informed consent form is dependent on whether the proposed changes are considered minor or major. The IRB Chair or designee shall have the final responsibility for this determination.

The IRB Chair or designee can expedite the review and approval of minor modifications to an IRB-approved research protocol or informed consent forms. A minor modification is a change that would not materially affect an assessment of the risks and benefits of the study, or does not substantially change the specific goals or design of the study.

Major modifications to an IRB approved research protocol or informed consent form must undergo full review and approval. A major modification is any change which materially affects an assessment of the risks and benefits of the study, or substantially changes the specific goals or design of the study.

**Serious or Continuing Noncompliance with Human Subjects Regulations or IRB Requirements**

The IRB reviews all allegations of noncompliance with human subjects regulations. Any individual or organization may submit a written complaint or allegation of non-compliance to the IRB. The IRB may also initiate a complaint based on information available to the IRB. Noncompliance means conducting research involving human subjects in a manner that disregards or violates government regulation or College IRB policy governing such research. This can include, but is not limited to, failure to obtain IRB approval for research involving human subjects, inadequate or nonexistent procedures for informed consent, inadequate supervision in research involving experimental drugs, devices or procedures, failure to follow recommendations made by the IRB to ensure the safety of subjects, failure to report serious adverse events and/or unanticipated problems or proposed protocol changes to the IRB, and failure to provide ongoing progress reports.

**Initial Inquiry**

Whenever an allegation or complaint of noncompliance is made, the Chair will forward the allegation to a member of the IRB (other than the Chair) with appropriate expertise. The Chair also will send written notice of the allegation(s) to the researcher and request a response from the researcher. The designated member is authorized to review the allegation of noncompliance, the response from the researcher and any other information necessary to determine whether a full investigation is warranted. At the conclusion of his or her inquiry, the member will make a recommendation to the IRB concerning appropriate action.

The IRB will promptly act upon the recommendations of the member and notify the researcher in
writing of the outcome of the inquiry. This notice will include a statement of the reasons for the IRB’s decision. Depending on the nature of the allegation(s) and the extent of the review required, the inquiry phase is generally expected to be completed within thirty days. The IRB may grant an extension of time if warranted. A formal IRB investigation is warranted where the allegation or complaint appears founded and is of a serious nature.

**Formal Investigation**

The IRB may decide to institute a formal investigation if it determines that an allegation appears founded and is of a serious nature. The investigation will be conducted by an ad hoc panel of three IRB members (other than the Chair) known as the Investigation Committee. The Investigation Committee will consist of IRB members whose areas of expertise are suited to reviewing the complaint and area of study. The Investigation Committee will also include the IRB member who conducted the initial inquiry. The Investigation Committee may use any and all materials and reports gathered during the initial inquiry phase. The Investigation Committee may obtain documents and other records relevant to the investigation and may interview any persons who may have information relevant to the complaint. The researcher under investigation will be given an opportunity to submit written comments and to appear before the Investigation Committee on at least one occasion prior to the Investigation Committee issuing its report. Based on its investigation, the Investigation Committee will prepare a report summarizing the information it considered and outlining its conclusions and recommended actions. The Investigation Committee will send the report to the IRB. Depending on the case, the investigation phase is generally expected to be completed within sixty (60) working days.

**Decision**

The IRB will consider the report of the Investigation Committee and any comments submitted by the researcher in reaching its decision. Actions the Committee may take with respect to the investigation include, but are not limited to:

1. Dismissal of the complaint as unjustified;
2. Remediation or educational measures;
3. Monitoring of research activities;
4. Increased reporting by the researcher of his/her human subjects research activities;
5. Restrictions on research practice, such as limiting the privilege to minimal risk or supervised projects;
6. Suspension of approval for one or more of the researcher's studies;
7. Termination of approval for one or more of the researcher's studies; or
8. Referral to other College officials or committees for possible further review and action by those bodies, including potential disciplinary actions up to and including termination in accordance with the appropriate disciplinary procedures for faculty, staff, and students.

The Committee will send a copy of its decision to the investigator.

**Action Prior to Decision**

At any time during the inquiry or investigation process, the IRB may determine that it is necessary to suspend enrollment of research subjects or to suspend approval of research project(s) to ensure the protection of human subjects. Except in cases of imminent harm to research subjects or others, the IRB will not suspend approval of research studies until the researcher has had an opportunity to respond to the initial allegation(s) of noncompliance.
Suspension and Termination
When the IRB makes a decision to suspend or terminate approval of research for any reason, the following individuals, in addition to the investigators listed on the protocol and the departments/institutions involved in the research, will be notified, where applicable:

1. College Provost;
2. IRB Chair of other institutions participating in research.

The IRB will give notice of such suspensions or terminations within five (5) working days.

Reconsenting of Subjects
Reconsenting subjects in the same research study may be required by the IRB whenever it determines that:

1. The risk/benefit ratio has shifted;
2. There are unanticipated findings involving immediate or potential risks to subjects; or
3. Any new information regarding the risks, benefits or conditions of study participation should be provided to subjects.

The IRB may also require that subjects be reconsented to inform them of an investigator’s desire to use or share data or tissue from previous research studies for future research purposes.

RESEARCH PROTOCOL RENEWALS
Annual renewal of all research protocols by the IRB is mandatory; all protocols even if there have been no changes since approval, must be renewed annually. This includes research protocols where human research subject accrual has been closed and research interventions completed, but data continue to be collected or analyzed. The IRB may require more frequent review of certain research protocols based on risk assessment. Investigators will be informed by the IRB of the expiration date of the approved research protocol. It is the investigator’s responsibility to assure timely submission of the research protocol for IRB renewal of re-approval prior to the expiration date. To submit, the investigator should complete a Research Study Renewal/Termination Report. If there are no changes to the approved protocol, the IRB will issue a one-year continuation. If there are any changes, the protocol must again be reviewed by the IRB.

The investigator will complete the Research Study Renewal/Termination Report and supporting information and submit it to the IRB. Research protocol renewals should be submitted to the IRB at least five (5) weeks prior to the expiration date of current approval.

The category of renewal review of the research protocol is dependent on the category of its original review and approval and the risk level of the research study.

Lapses in IRB Approval
If the research study is not reviewed and approved by the IRB prior to the expiration date of the previous IRB approval, the investigator will be required to cease all research activities described in the research protocol until notification of final IRB approval for continuation of research.
If the research is submitted for IRB renewal and approval prior to expiration date of previous approval, but the expiration date lapses prior to IRB granting final approval, all research activities must cease.

If the research is not submitted for continuation of IRB approval prior to the expiration date of the previous IRB approval, the investigator shall be sent written notification that IRB approval of research has expired, and the research must stop.

COMMITTEE RECORDKEEPING AND REPORTING REQUIREMENTS

Committee Minutes
The minutes of IRB meetings must include all the information stipulated by HHS regulations at 45 CFR 46.115(a)(2). The minutes of IRB meetings will document, among other things:

1. Separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB;
2. All applicable waivers of required informed consent;
3. The vote on all IRB actions including the number of members voting for, against, and abstaining. In order to document the continued existence of a quorum, OHRP recommends that votes be recorded in the minutes using the following format: Total = 15; Vote: For-14, Opposed-0, Abstained-1.

The IRB Committee will note all discussion regarding submitted protocols in its minutes. Federal regulations will be cited where applicable. IRB meeting minutes are available in electronic format on the SUNY Delhi IRB shared drive.

Principal Investigators’ Reporting Requirements
Investigators are responsible for reporting the progress of their research to the IRB as often as and in the manner prescribed by the IRB, but no less than once per year. Investigators will be asked to complete a Research Study Renewal/Termination Report. For terminated research protocols, a final progress report shall be submitted within 30 days to the IRB office.

Principal Investigators must also promptly report, to their department heads and to the IRB, any injuries to human participants, any serious adverse events, and/or any unanticipated problems that involve risks to the human participants or to others. In addition, these situations must be included in the final Research Study Renewal/Termination Report submitted to the IRB. Please see the section of this document entitled “IRB Enforcement and Monitoring” for additional information about serious adverse events and unanticipated problems.

IRB Reporting Requirements
The Chair of the IRB committee shall be responsible for promptly reporting information on a variety of issues, as appropriate, to the IRB, to the Office for Human Research Protection (OHRP), and to research investigators and department heads. Specifically, the IRB shall:

1. Report promptly to the OHRP significant instances or material findings of injuries to participants, serious adverse events, and/or unanticipated problems involving risks to participants or others;
2. Report to the IRB information received concerning non-compliance by research investigators, injuries to participants, serious adverse events, and/or unanticipated problems involving risks, changes proposed to research activities, and the progress of the research;
3. Maintain information concerning the IRB’s reasons for the termination or suspension of IRB approval; and
4. Report promptly any changes in IRB membership to the OHRP.

The IRB shall have the authority to and be responsible for promptly reporting information to the OHRP. In conjunction with this requirement, the IRB must be prepared to receive and act upon information received from a variety of sources, such as human participants, research investigators, the Grants Office, or other institutional staff. For reporting purposes, the IRB will follow the procedures described herein:

1. Any serious or continuing noncompliance by research investigators with the requirements of the IRB: This information shall be reported promptly to the IRB and the OHRP;
2. Injuries to human participants: Information received by the IRB concerning injuries to participants shall be reported promptly to the IRB (the IRB is then responsible for reporting to the OHRP);
3. Serious adverse events and/or unanticipated problems: Information received by the IRB concerning serious adverse events and/or unanticipated problems involving risks to participants or others shall be reported promptly to the IRB (the IRB is then responsible for reporting to the OHRP);
4. Suspension or termination of IRB approval: Each IRB suspension or termination of approval of research protocols shall include a statement of the reasons for the IRB’s actions; the IRB shall report the action promptly to the research investigator, the IRB, and the OHRP;
5. Actions taking place outside of full IRB meetings (determination of exempt status, etc.) shall be reported promptly to the IRB.

RENEWAL OF AND CHANGES TO IRB POLICIES AND DOCUMENTS

This document, including associated forms, will be reviewed and updated by the IRB as may be necessary or appropriate to ensure fulfillment of institutional responsibilities, to improve operational efficiency, or to address other concerns that may arise. All revisions will be dated and appended as an addendum until such time as a revised version of this document (or the applicable pages) is prepared.

No policies, procedures or forms of IRB may be changed, implemented or amended without the approval of the IRB. All such documents will contain the date of approval (or the date of last revision). IRB will maintain a catalogue of its approved policies, procedures and forms. Any person wishing to suggest a new or revised policy, procedure or form is invited to submit the request in writing to the Chair, along with an explanation of the need for the change (e.g., improved efficiency).