State University of New York
State College of Optometry
Institutional Review Board Committee
(IRBC)

IRBC
Policies and Procedures Handbook for Investigators

This document is available on the Web at:
http://www.sunyopt.edu

Office of Research Compliance/
Office of the Associate Dean for Graduate Studies and Research

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Institutional Review Board Committee (IRBC)

General Information

This handbook, based in part on OHRP's "written institutional review board procedures" (http://ohrp.osophs.dhhs.gov/g-topics.htm) is also an elaboration of campus policy on "Research Involving Human Subjects". This policy 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.

State College of Optometry has a Federal-Wide Assurance (FWA #1460) on file with Office for Human Research Protections (OHRP; subdivision of the Department of Health and Human Services). This document provides written assurance that all research conducted at this institution that involves human subjects will be in compliance with the Federal Policy for the Protection of Human Subjects, specifically 45CFR46, and 21CFR50 and 21CFR56 (for clinical research activities regulated by the FDA).

The basic ethical principles that underlie the Federal Policy are summarized in The Belmont Report. These regulations, specifically covering research from grants funded by the National Institutes of Health, have been adopted by State College of Optometry to cover ALL research activities involving human subjects, regardless of source of funding.

IRBC operates in compliance with Sections 3 and 5.11 of the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice.

The Institutional Review Board Committee (IRBC) is the only designated Institutional Review Board for the College. IRBC is 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 IRBC' membership, and the number of members on the committees is in accordance with the Federal Policy.

Members of IRBC are recommended by the Associate Dean for Graduate Studies and Research (and recommended to the Vive President for Academic Affairs and to the President of the College), as designated on State College of Optometry's FWA, following consideration of recommendations from applicable administrators, current IRB members, and/or members of the community (for non-University positions). Members are appointed for a renewable, one 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 Associate Dean, with consultation with the IRBC chair as needed, to determine if appointments will be renewed. Appointments of Chair and co-Chair are recommended by the Associate Dean whose decision is based on length and quality of service to the committee, as well as leadership ability. There is no remuneration for individuals serving as IRBC members. No IRBC 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 co-chair of the IRB shall serve as the chair for:

- When the chair has a conflict of interest, and for
- Time-sensitive matters pertaining to human subject protections when the relevant IRB chair is unavailable.

Since the IRBC is a constituted committee of the State University of New York (SUNY), liability coverage is provided by SUNY for members serving on the committee (excluding personal liability coverage).

The Associate Dean or the Chairperson of the IRBC shall conduct an orientation for new members in which training and relevant materials are provided (Belmont Report, federal regulations, University Policy, IRBC Guidelines), and the details concerning committee function and procedures are discussed.

IRBC may, at its discretion, invite individuals with competence in special areas (Consultants) 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 IRBC meetings to clarify issues with the members concerning their proposed research activity. Such guests do not take part in committee deliberations or voting.

IRBC reports to the Associate Dean for Graduate Studies and Research. The Associate Dean attends policy or recommended IRBC meetings, and, is kept apprised of committee actions via receipt of all committee minutes. The Associate Dean is consulted regularly on matters pertaining to human subject protections. The Office of Research Compliance (ORC), within the Office of the Associate Dean for Graduate Studies and Research is responsible for regularly monitoring IRBC' and investigator compliance, and updating IRBC' policies and procedures with current and/or new relevant federal or state regulations.

The Associate Dean or staff within the ORC serve as liaisons between the research investigators and IRBC. The administrators provide administrative and secretarial support for the committee, and assist the investigators through the application and approval process. They act on behalf of the committee and University when providing assurance of human subjects approval to sponsoring agencies, or when dealing with regulatory agencies.

The IRBC or the Associate Dean routinely circulates important correspondence pertaining to research involving human subjects to the IRBC-approved investigators and other researchers. The Associate Dean may meet with Chairs, their administrative assistants, and their faculty to discuss IRBC policies and procedures, and federal regulations that govern clinical research.
Correspondence (including application materials) to IRBC may be directed to:

Associate Dean for Graduate Studies and Research
SUNY, State College of Optometry
33 West 42nd Street
New York, N.Y. 10036
Telephone: (212) 780-4986
Fax: (212) 780-5137

Applications, guidelines, policies, important announcements and relevant links pertaining to research involving human subjects are available at:
http://www.sunyopt.edu/research/res_inst_poli.shtml

The IRBC recommends visiting this site frequently for up-to-date information concerning research involving human subjects at State College of Optometry. Applications to the committees should be obtained directly from this site to ensure that the most current versions are being used.

Section 1
State College of Optometry Definitions

A. Human Subject: a living individual about whom an investigator conducting research obtains data

a) directly, through intervention or interaction with the individual

or

b) indirectly, through study of the individual's existing data and/or biological specimens

B. Minimal Risk: means that 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.

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

Section 2
Categories of Research Requiring IRBC Approval

A. Exempt Review Category
Research activities qualify for exemption status (i.e., exemption from committee member review), as long as the activity fits into one of the categories below **and** the activity involves no foreseeable risk.

Note that the exemptions below do not apply to research involving prisoners, fetuses, pregnant women, or non-viable or questionably viable neonates.

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 use 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

The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with minors (17 years old or younger) except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

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.

IMPORTANT NOTE PERTAINING TO EXEMPTION #4:

a) STATE COLLEGE OF OPTOMETRY has specific policies regarding biological specimens. See sections 18 and 19 for details.

b) STATE COLLEGE OF OPTOMETRY waives the requirement for submission of exemption application materials for activities involving only the re-analysis ('secondary analysis) of data that had previously been collected from human subjects as part of a prior study, provided that:

i. the data will be analyzed in an anonymous manner

and

ii. the prior study was conducted under IRB approval (where applicable, e.g., research on census data would be covered by this waiver, but IRB approval in this instance would not be relevant.)

This waiver includes re-analysis of publicly available datasets, provided the 2 conditions cited above apply.

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 Procedure: If the investigator determines that his/her proposed research activity involves no risk, **and** falls into one of the exemption categories, s/he can check off a request for Exempt Review. The IO initially reviews the request and then forwards it to the IRB chair. The Chair makes the primary determination. Once the decision has been made, the IRB chair will notify the investigator in writing regarding the status of the application. Notification will indicate that the application was fully approved, or that it required modifications/clarifications in order to secure approval. Approval is granted for 1 year, and the principal investigator is required to submit continuing review materials in sufficient time to avoid any lapse between approval periods. Administrative review is also written to the PI by the IO indicating institutional approval to conduct the IRB-approved exempt research study.

B. Expedited Review Category

NOTE:

- Research activities that present no more than minimal risk to human subjects, AND involve only procedures listed in one or more of the following categories, *may* be reviewed by IRBC through the expedited review procedure described below.
- The categories in this list apply regardless of the age of subjects, except as noted.
- **The expedited review procedure 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, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.**
- Categories one (1) through seven (7) below pertain to both initial and continuing IRB review.
- IRBC can review minor changes to research approved by the full committee via the expedited review procedure. IRBC defines a minor change as one that has no substantive effect upon, or reduces, the protocol risk already approved by the full committee as being acceptable research risk.

Expedited Research Categories

1. 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.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   - from healthy, nonpregnant adults who weigh 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 (persons 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.

3. Prospective collection of biological specimens for research purposes by noninvasive means. (Note that STATE COLLEGE OF OPTOMETRY has specific local policies regarding biological specimens. See sections 18 and 19 for additional guidance)

   Examples:
   - Hair and nail clippings in a non-disfiguring manner;
   - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   - permanent teeth if routine patient care indicates a need for extraction;
   - excreta and external secretions (including sweat);
   - uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
   - placenta removed at delivery;
   - amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   - supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic

scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- sputum collected after saline mist nebulization.

4. 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:
   - 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;
   - magnetic resonance imaging;
   - electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   - moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. 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). (Note: See section 2.A for similar research that may fall into the exempt category. This listing refers only to research that is not exempt.)

*STATE COLLEGE OF OPTOMETRY has specific policies regarding data registries and biological specimens. See sections 18 and 19, respectively for details.

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

7. 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. (Note: See section 2.A for similar research that may fall

into the exempt category. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the full committee as follows:
   (a) Where:
      - the research is permanently closed to the enrollment of new subjects;
      - all subjects have completed all research-related interventions; and
      - the research remains active only for long-term follow-up of subjects; or
   (b) Where no subjects have been enrolled and no additional risks have been identified; or
   (c) 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 IRBC 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 Procedure: Once the IO (Associate Dean) receives an IRB proposal, it is forwarded to the IRB chair who determines if a research application meets all criteria for expedited review (e.g., minimal risk, applicability to one of the categories referenced above). The application materials are sent to one or more experienced reviewers, chosen from among the members of IRBC. **In reviewing the research in the expedited review category, the reviewers may exercise all of the authorities of IRBC 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 regarding the status of the application. This written notification will indicate that the application was fully approved, required modifications/clarifications in order to secure approval, or deferred for full committee review.

Approval is granted for 1 year, and the principal investigator is required to submit continuing review materials in sufficient time to avoid any lapse between approval periods. The approval letter also contains a notification from the IO as to the granting of administrative approval to carry out the IRB-approved study.

IRBC receives and notes a report at the monthly meeting of all applications that have been reviewed and approved using the expedited review procedure.

C. Full Review Category

All other research (i.e. non-exempt, non-expedited) will be reviewed by IRBC at one of its convened meetings. The schedule of meetings is available from the IO or the IRB chair.

A quorum (majority) of members, including at least one non-scientific member, must be present for a meeting to be held. Copies of all protocols to be reviewed at the meeting are distributed to the members approximately 7 days before the meeting. Each protocol is assigned to all IRBC reviewers who present the protocol and begin the committee deliberations. All members get all materials outlined in Section 3, except that on some occasions, only the primary and secondary reviewers get the full protocol, while the remainder of the members get the project summary.

After the meeting, the investigator is notified regarding the status of the application. The application may be approved, require clarifications/ modifications in order to secure approval, deferred (i.e., response from investigator must be brought back to full committee), or disapproved. IRBC policy requires that no more than five (5) separate applications from a single investigator may be on the agenda for review at a convened meeting. Requests for waiver of this policy will be considered on a case by case basis by the Chair of IRBC.

Approval periods of projects requiring full committee review (initial or continuing) are dependent on the degree of risk associated with a study, and cannot extend beyond the 1 year anniversary (minus 1 day) of the convened committee review date. For example, if a study was reviewed by the full committee on November 11, 2002, the expiration date will be no later than November 10, 2003 no matter when the final approval date might be.

Certain projects may require review more often than annually based on other factors, aside from degree of risk, e.g., past history of non-compliance with a particular investigator, requiring more stringent oversight by the committee.

Section 3
Materials Required For Submission to IRBC

Research activities that involve human subjects, as described in the categories mentioned in the previous section, must be filed with IRBC and must be approved prior to commencement of the activity. Each principal investigator must submit one e-mail attachment in .rtf' format and one hard copy signed by the PI to the Associate Dean for Graduate Studies and Research. Following review for institutional approval, The Associate Dean will then forward it to the chair if the IRBC. The review by the Associate Dean can result in disapproval to conduct a study that has been approved by IRBC. However, The Asssociate Dean cannot approve a study that has been disapproved by IRBC.

Materials required for submission include:

A. **IRBC application, complete with the following signature:**
- Signature of the principal investigator, who ensures accuracy of the information contained within the submitted materials, and, upon approval, assures compliance with all aspects.

B. **Project description** that 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:
- Discussion of the scientific significance and goal of the study,
- Description of subject recruitment procedures, including copies of all advertisements, posters, etc. to be used,
- Inclusion/exclusion criteria for subject entry. Include (federally-required) justification if women, minorities and/or minors are to be excluded in the research activity. Disclose if investigator proposes to include him/herself, or members of his or her family as subjects in the proposed research.
- Potential risks and benefits to subjects
- Highlights of potential problems related to risk/benefit, confidentiality, or other ethical problems. The Office of Research Compliance should be contacted for information concerning Certificates of Confidentiality if a principal risk of the study is breach of confidentiality (i.e., where such a breach could place the subject at risk of, e.g., criminal or civil liability, or damaging to the subject's financial standing, employability, or reputation).
- Copies of all interviews, surveys, questionnaires etc. should be submitted for review.
- The identification of vulnerable groups that may be encountered in the subject population, and additional protections that will be put into place to ensure that the rights and welfare of such groups are protected. Examples of such individuals include pregnant women, fetuses, minors, those who are unable to consent for themselves, economically disadvantaged, and/or educationally disadvantaged.
- Details of the process by which the capacity to consent will be assessed for all subjects. To satisfy this requirement, please refer to OHRP Guidelines on the Capacity to Provide Consent for Research (Including Research Involving Subjects with Diminished Capacity), also available at http://www.sunyopt.edu

C. When **external funding** is being sought from an external agency (NIH, NSF, pharmaceutical company, etc.), the grant or sponsor protocol should be submitted (in addition to, not in lieu of, the project description). An electronic copy as well as a hard copy is required.

D. **Consent, Permission, or Assent form(s) printed on SUNY Optometry Departmental letterhead** and standardized to conform to IRBC-required format (which provides detailed information about the informed consent process, obtaining consent from non-english speaking subjects, and guidance on writing consent forms). See the SUNY College of Optometry webpage following the links from Research to Policies.

Section 4
Review Time Considerations

IRBC recommends consultation with the Office of the Associate Dean for Graduate Studies and Research early on in the planning stages of research in order to facilitate the coordination the various deadlines to which the activity may be subject for review. There are separate campus committees that are federally and/or state mandated to review research for compliance with regulations that govern involvement of animal subjects as well as human subjects.

The length of time required for review of an application by IRBC is necessarily dependent on the review category into which a given application falls:

- Exempt category projects are reviewed, and investigators are notified, generally within 2 weeks of receipt date by the ORC.
- Projects qualifying for expedited review are sent out to committee members on regular basis. Review is completed generally within 3 weeks of receipt date.

The deadlines for applications requiring full committee review at a convened meeting of IRBC is approximately 2 ½ weeks prior to meeting date. Full board review meetings are scheduled as needed.

For research in which outside funding is being sought, it is recommended that IRBC materials be submitted far enough in advance of the grant submission deadline to allow for 2 successive meetings of IRBC**.**

Section 5
Criteria For IRBC Approval of Research

In order to approve a research activity, IRBC must determine that all of the following requirements are satisfied:

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

- Informed consent is obtained in compliance with IRBC policy as outlined in these guidelines
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- **Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**
- 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.
- All personnel associated the research who either deal directly with the human subject, or with human tissue and/or data, have successfully completed State College of Optometry's training program on the protection of human subjects in research. Details concerning the State College of Optometry's training program are provided in Section 17.

Section 6
Approval Periods

If the conditions above are satisfied, IRBC approval periods are granted on the basis of degree of risk associated with the particular protocol (but no greater than one year). In the case of full committee reviews, this one year criterion commences on the date the application was reviewed by full committee, *not the date the application receives final approval.* As mentioned previously, certain projects may require review more often than annually based on other factors, aside from degree of risk, e.g., past history of non-compliance with a particular investigator, requiring more stringent oversight by the committee.

A IRBC project may be renewed a maximum of four (4) times, after which time a new, complete application will need to be submitted for review, incorporating all amendments, updated consent, permission, and assent forms, funding information etc. that have occurred since the study's inception.

Research that has been approved by IRBC will be subject to further appropriate institutional review. Recommendations (approval signatures) for administrative approval should be sent to the The Associate Dean for Graduate Studies by the Department Chair, and The Vice President for Clinical Affairs as well as the Chief of Clinical Service (if appropriate). **However, those officials may not approve research if it has not been approved by IRBC**. The Associate Dean for Graduate Studies and Research will notify the Chair of the IRB and the PI is administrative approval is given.

Section 7
Responsibility of Investigators Conducting IRBC-Approved Activities

Once his/her project is approved by IRBC, the investigator must:

- conduct every aspect of the project as approved by IRBC,
- promptly report any revisions or amendments to the research activity for review and approval by IRBC prior to commencement of the revised protocol (including changes in personnel). The only exception to this policy is in situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject,
- promptly report any unanticipated problems involving risks to subjects or others,
- assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials,
- where consent/permission/assent form(s) have been approved for the research activity, only IRBC-approved, stamped forms may be used in the consent process, and
- Assume full responsibility for assuring that all personnel who s/he has delegated to obtain informed consent from subjects has complete understanding of the research protocol, and of the consent process (including assessment of the subject to give consent for participation)

Section 8
IRBC Disapproval

Disapproval of an activity is determined at meetings of the full committee only.

If IRBC does not approve a research activity, the principal investigator has the right to appeal that decision either in writing or in person at a IRBC meeting. If the investigator is not satisfied with the decision subsequently reached by IRBC, s/he may request re-review by IRBC whenever significant changes are made to the research protocol or significant new information becomes available.

Section 9
Vulnerable Populations:
Research Involving Pregnant Women, Fetuses, Nonviable Neonates, and Neonates of Questionable Viability

(reference 45CFR46 Subpart B-rev 12/01)

(Note that viable neonates are considered minors, and are therefore covered under section 10, in compliance with 45CFR46 Subpart D)

A. Definitions

fetus: the product of conception from implantation until delivery
neonate: a newborn

nonviable neonate: a newborn that, although living after delivery, is not viable
viable: being able to survive to the point of independently maintaining heartbeat and respiration. If the neonate is viable, it is covered by subpart D (minors).

Those involved in the research must have NO PART in any decisions as to the timing, method or procedures used to terminate a pregnancy (and must provide NO inducement to do so), OR in determining the viability of the neonate.

B. For Research involving Pregnant Women or Fetuses, IRBC must determine:

- Where scientifically appropriate, pre-clinical (animal) studies, and clinical studies have been done on non-pregnant women to assess potential risks to women and fetuses
- Risk to fetus must be either:
  -caused by procedures holding out the prospect of direct benefit for the woman or fetus
  OR
  -if no direct benefit, risk to fetus must be 'minimal', and purpose of research is to 'yield important biomedical knowledge which cannot be obtained by any other means.
- 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 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.

C. For Research Involving Neonates (non-, or questionably viable)

IRBC must determine that where scientifically appropriate, preclinical and clinical studies have been done for assessing potential risks to neonates.

1. Neonates of Uncertain Viability:

Until it has been determined whether or not a neonate is viable, the neonate must not be included in research unless:

- The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and the neonate is subject to the least possible amount of risk to **achieve it**

OR

- Purpose of the research is the development of important biomedical knowledge which can't be obtained by any other means, and there will be no added risk to the neonate resulting from the research

AND

- Consent from EITHER parent is obtained (or if neither is available, competent etc, either parents legally authorized representative can do so).

2. Nonviable Neonates:

After delivery, such neonates may not be involved in research unless all of the following conditions are met:

- Vital functions of the neonate will not be artificially maintained
- The research will not terminate the heartbeat or respiration of the neonate
- There will be no added risk to the neonate resulting from the research
- Purpose of the research is the development of important biomedical knowledge which can't be obtained by any other means,

AND

- Consent of both parents of the neonate is obtained. Waiver and alteration possibilities allowed by 46.116 (c and d, see handbook section 12.A) can't be applied. If either parent is unable to consent, as outlined in above sections, the informed consent of the other parent will suffice. The consent of the father is not needed if the pregnancy resulted from rape or incest. Consent of legally authorized reps of either or both parents of a nonviable neonate will NOT SUFFICE to meet the requirements of this section.

Section 10
Vulnerable Populations:
Research Involving Minors
(In NY: less than 18 years old)

(reference: 45CFR46 Subpart D)

A. Additional Protections of Minors:

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

1) obtaining parental permission in most cases. The exception being 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 as subjects in the research 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.A. Sections 12 (General Issues in Informed Consent) and 15 (Consent (Permission)/Assent Requirements: Minor Subjects) should be reviewed for full details concerning the documentation of parental permission.

2) obtaining minor assent, except where IRBC specifically grants a waiver. In determining whether children are capable of assenting, IRBC must take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child.

If IRBC determines that:

- the capability of some or all of the children is so limited that they cannot reasonably be consulted, **or**
- that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

Even where IRBC determines that the subjects are capable of assenting, the assent requirement can still be waived under circumstances in which consent may be waived, as outlined in section 12.A.

IRBC may require documentation of assent, such that the minor is presented with an assent form to review and sign. Sections 12 (General Issues in Informed Consent) and 15 (Consent (Permission)/Assent Requirements: Minor Subjects (less that 18 years old) should be reviewed for full details concerning the documentation requirements.

3) allowance of participation in only certain categories of research. The three main categories are:

a) minimal risk,
b) more than minimal risk with the possibility of direct benefit
and
c) more than minimal risk without the possibility of direct benefit, BUT all of the following conditions must be met:

- The risk must represent a minor increase over minimal risk;
- 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;
- The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

d) the assent of the minor subject and permission from BOTH parents/guardians are solicited, in accordance with 45CFR46.

B. Types of Activities involving minors that qualify for exemption or expedited review

1. **The exempt review category**, and corresponding review procedure, as outlined in Section 2.A of this handbook, 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 old 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 category**, and corresponding review procedure, as outlined in Section 2.B, is applicable to research involving minor subjects, as long as the particular activity in that section does not require that the subject be 18 years old or older.

3. All other research involving minor subjects must be reviewed by the full committee, as discussed in section 2.C.

C. When enrollment of minors is possible, but rarely anticipated

For those studies where minors will be included, but rarely, IRBC may waive the requirement for submission of a parent permission form and minor's assent (if applicable) as a condition for study approval. However, these documents will need to be submitted for review and approval prior to enrollment of minors into the study.

D. Involvement of Minors in the Departmental Subject Pools

No high school students working at the institution may participate in experiments unless prior approval for use of this specific subject population is granted by IRBC for a given experiment. Parental permission, and subject assent, will be required.

College students who are under the age of 18 may participate in studies that are specifically approved for the use of minors. Further, unless a waiver of parental permission has been requested by the investigator, and granted by IRBC, permission of the parent of the minor subject will need to be obtained (see section 10.A and Section 12.A for conditions that need to be satisfied for such a waiver to be granted). Regardless of whether or not such a waiver is granted, assent of the minor subject will be required in all cases. Referenced approvals and waivers will be granted for projects for which the risks to the subject are determined by the committee to be minimal.

No student, minor or otherwise, can be required to participate in research using human subjects, as participation in such activities must be voluntary.

Section 11
Vulnerable Populations:
Research Involving Prisoners
(reference: 45CFR46 Subpart C)

At the present time, research involving prisoners is not conducted at STATE COLLEGE OF OPTOMETRY due, in part, to the fact that our membership is not constituted as required in Subpart C of the federal regulations at 45CFR46.

Section 12
General Issues in Informed Consent

No investigator may involve a human being as a subject, or use their tissue or data, in a research activity unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative. There are limited conditions under which this requirement is waived.

A. Criteria for a Waiver of Obtaining Informed Consent

There are two main exceptions to the requirement for obtaining consent:

1. When IRBC finds that ALL of 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; and
   (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

An investigator may request a waiver of informed consent by providing evidence that the conditions above are met for his/her research activity.

or

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*. Section 20 (Exemptions from IRBC Approval Requirement) should be reviewed for details.

B. Criteria for a Waiver from the Documentation of Informed Consent

The federal regulations allow for a waiver of the documentation of consent (i.e., a signed consent form) if one of the following conditions are met:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
or
(2) That 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.

Investigators may specifically request a waiver of the documentation of the informed consent requirement by providing information that supports one of the 2 conditions above. None the less, IRBC will still require submission of either a consent 'script' (i.e., to verbally consent a subject, e.g., over the phone) or a consent letter that does not require the subject to sign, but to, e.g., complete an attached survey. In the latter case, 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)'

Both methods will need to comply with federal requirements regarding mandated elements of informed consent.

C. Differences between consent, permission and assent

1. Consent forms are used to consent subjects 18 years or older.
2. 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).
3. Assent forms are used to obtain agreement from the minor subject to be in the study.

D. Obtaining Consent from Non-English Speaking Subjects

An important aspect of the consent process is to provide the information in a language understandable to the subjects. IRBC recognizes 2 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 IRBC before use of the consent form.

or

2. The former Office for Protection from Research Risks (OPRR , **now OHRP**: Office for Human Research Protections) offers guidance on 'Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English', which IRBC formally accepted on February 22, 2001, as adequately protecting the rights of non-English speaking subjects. This method involves use of a IRBC-approved English language consent form, a IRBC-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 at:
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ic-non-e.htm

E. Circumstances Under Which Consent Must be Sought

The consent process is one of the most important elements of all research studies involving human subjects. If consent is not obtained properly then the rights of the individual research subject have been violated.

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.

An assessment of capacity to give consent must be performed in ALL subjects. Section 13 provides full detail on this requirement.

Section 13
Capacity to Provide Consent for Research
(including Research Involving Subjects with Diminished capacity)

A Introduction

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.

This section addresses consent issues in adult subjects only. Consonant with legal requirements on research involving minors, it is generally accepted that minors are not

capable of consenting to research activities. This is due to an immaturity in decision-making skills (rather than an impairment). Parental permission and assent issues governing research involving minors are specifically addressed Sections 10 and 15 in this handbook

B. First step in the process: IRBC Review

1) During the review of a project, IRBC makes an assessment of the risk and therapeutic benefit associated with the study procedures. Risk can be considered minimal, i.e., the level of risk encountered in the subject's daily life, or more than minimal risk. The study may contain no benefit, direct benefit, or indirect benefit (benefit to society, i.e., provides information about the disease in general).

2) Based on this assessment, IRBC will determine what type of review the study can undergo (exempt, expedited, or full committee) and will determine if the proposed subject populations are acceptable for inclusion. Capacity to consent (described below) is one factor that is considered in this determination:

a. **Subjects who lack the capacity to consent for themselves can be included in studies <u>only</u> if IRBC confirms that one of the following criteria is met:**

- risk is minimal (defined in the federal regulations as "the probability and magnitude of harm anticipated in the research are not greater in and of themselves than those encountered in daily life, or during the performance of routine physical or psychological examinations or tests")

OR

- risk is more than minimal, but there is a possibility of direct benefit to the subject.

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 only with added procedural requirements, to be addressed by IRBC.

3) As a result of review, any additional safeguards (e.g., type of capacity assessment) required by IRBC 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.

C. Required Procedures to be followed by the Person Obtaining Consent for <u>All</u> Studies, <u>All</u> Subjects:

The individual who signs the consent form as the 'Person obtaining consent' is responsible for leading the potential subject through the entire consent process. This means:

1) all aspects of the study, as described in the consent form, are first discussed with the potential subject,

2) the consent form is thoroughly reviewed with the potential subject and answers to the potential subject's questions are provided
3) while reviewing the consent form, the person obtaining consent asks questions designed to assess the potential subject's understanding of the material. The person will specifically state this intent to the potential subject (i.e., the person is making sure the potential subject appreciates what s/he is being asked to do, and why).
4) the potential subject is given ample opportunity to decide, without coercion or undue influence, whether or not to be in the study.
5) The consent process does not end with the formal signing of the consent document. Rather, it is an ongoing process that continues throughout the subject's participation in the study. The person obtaining consent remains responsible for continued assessments of the subject's understanding of what is happening to him/her, his/her willingness to participate and for providing the subject with any new information that may affect the willingness to participate.

It is the Principal Investigator's responsibility to train and supervise the study personnel who are obtaining consent.

D. What determines a potential subject's capacity to consent to research?

For the purpose of this section, a subject has the capacity to consent to his or her own participation in a research activity if s/he demonstrates an appreciation:

1) that the activity is research, not standard treatment
2) of the risks and benefits of a study
3) of the alternatives that are available ~~is~~ if s/he does not participate
4) that, if s/he chooses not to participate, this decision will be accepted without penalty, i.e., without jeopardizing clinical care.

In reaching a decision about participation, it is essential for the potential subject to demonstrate an ability to use this information in a rational manner. Thus, in considering risks, benefits, and available alternatives, subjects must show they understand the aspects of these factors that are unique to them as individuals. To highlight this distinction, a person who is suffering with severe depression may be able to demonstrate an *appreciation* of a, b, c and d above, but may not care, or may actually want to take risks. Such individuals should not be considered able to provide consent for themselves.

E. What characteristics of research subjects may suggest a diminished capacity to provide consent?

1) Certain individuals, such as those with severe dementia, or severe mental retardation, will have a diminished capacity to provide consent. For these individuals, see the section on 'Surrogate Consent,' below.

2) For other individuals, it will not always be easy to predict whether capacity will be diminished given the following:

a) Many individuals with psychiatric illnesses have the capacity to provide consent.

b) Medical illnesses (e.g., cerebral insult) may be accompanied by an impaired capacity to consent.

c) Upon learning of a serious diagnosis (e.g. cancer), psychological "shock" may temporarily impair a person's capacity to provide consent, although the illness does not affect decisional capacity in and of itself**.**

d) Individuals who are intoxicated with alcohol or with drugs may be unable to consent to research until the intoxication resolves.

3) In assessing capacity, it is important to note that it is neither a constant nor an absolute. For example:

a) Stroke victims may not have the capacity to consent to research immediately after the onset of stroke, but may develop capacity as recovery progresses.

b) Patients in the early stages of Alzheimer's disease may initially have the capacity to consent to research, but as the disease progresses, may lose the ability to decide to continue or withdraw from that research.

c) Patients with schizophrenia often experience acute psychotic episodes followed by periods of lucidity.

d) Patients who learn they are terminally ill, often experience an initial short-lived period of emotional shock and denial which impairs their capacity to provide consent

4) The requisite level of capacity will necessarily vary from study to study and will depend on:

a) the complexity of the information being presented, and

b) the relative risks and benefits of the study (deciding to participate in a blood drawing protocol is 'easier' then deciding to participate in an experimental drug trial).

Therefore, when developing a research proposal, the investigator must determine whether the study will include any subjects who may not have the capacity to consent to the research, either initially, or at some point during the course of the study. If some or all subjects may have a diminished capacity to consent, the investigator must further determine if the potential impairment is temporary (e.g., 'shock' at the discovery of a medical diagnosis, intoxication), permanent (e.g., severe mental retardation), progressive (e.g., Alzheimer's dementia) or fluctuating (e.g., bipolar disorder).

F. If a study proposes to include a subject population where all or some of the individuals will lack the capacity to consent…

…IRBC will make first make a determination of risk/benefit category. As addressed above, in order to be considered for inclusion of this population, the study must necessarily involve either minimal risk, or more than minimal risk with the possibility of direct benefit.

If the study can include this subject population, the committee will next make the determination of whether or not a formal attestation/documentation of capacity assessment is required for each subject. An independent assessment of capacity* may be required in instances where, e.g., the research involves more than minimal risk, or, the research team does not include a physician or mental health professional who could be called upon to make the formal assessment. The above determinations will take into account the psychiatric, medical, and emotional status of the subject population, as well as the inherent risk/benefit ratio of the study design.

If IRBC requires such formal documentation of a subject's capacity, the following statement is added to the end of the consent form:

"My signature below attests to the fact that I am a physician or mental health professional and I have interviewed (name of patient) on _____(date). I have determined that s/he does_____ does not_____ have the capacity to consent to participation in this research activity, in that s/he is____ is not____ capable of appreciating a) that the activity described in this consent document constitutes research, not standard treatment, b) the risks and benefits of this study c) the alternatives that are available if s/he chooses not to participate, and d) that the decision to not participate will be accepted without penalty, i.e., without jeopardizing his/her clinical care."

*(i.e., by an MD or mental health professional not associated with the study, with familiarity with capacity to consent issues in human subjects research)

G. Who can provide consent for a patient to participate in a research study if a patient is incapable of doing so?

Reminder, such patients can only be enrolled in minimal risk research, or more than minimal risk research where direct benefit is possible.

1) **Individuals who may consent on behalf of the patient include:**

a) Individuals granted legally documented authority to make decisions ***specifically regarding participation in research activities***

b) Family Member (in order of priority: spouse, adult child, parent, adult sibling).
c) Individuals named in a health care proxy, only for those research protocols generally recognized in the medical community as offering the optimal treatment choice (e.g., there are few, if any, effective treatments for patients with multiple-recurrent cancer, and those with very rare or highly aggressive cancers. In such circumstances, the medical societies, including the National Cancer Institute, specifically recommend enrollment in a research protocol as the best possible care)

2) For studies in which the patient is able to provide initial consent, but may lose the capacity to decide whether to continue or withdraw consent during the study as a result of disease progression (e.g., Alzheimer's disease), IRBC recommends that the formal designation

of a surrogate (via execution of the document presented in #1 above) be discussed with the subject early on in the research activity.

3) Individuals who consent on behalf of a patient should be informed that they must make the decision for or against participation based on 'substituted judgment', reflecting views that the potential subject expressed while capable of making their own decision. If the views are not known, the decision should be based on what is believed to be in the best interests of the subject.

4) Individuals who consent on behalf of a patient 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, as described earlier in this section.

5) Assent from the patient should be obtained whenever possible. No subject should ever be enrolled, or continued in a research activity against their will.

6) Further, if an individual consents on the subject's behalf, the subject's capacity should be routinely assessed throughout the study (as reasonable with respect to the subject's disease state or disorder). If the subject regains the capacity to consent, s/he should be presented with the information about the study, as in the initial consent process, and be given the opportunity to decide to continue or withdraw from the study.

H. Conclusion

Obtaining ethically valid consent from all subjects in clinical studies is essential to the research program at SUNY, Optometry. IRBC hopes that this section will be of assistance to investigators in developing new protocols, and in assuring that current research activities provide maximal protection of human subjects.

Section 14
Required Format for Consent Forms: Adult Subjects
(18 years old and older)

Introduction:

All consent forms MUST

- be printed on departmental letterhead,
- 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 AND
- follow the format, including headings, given below:

Departmental Letterhead

Project Title:
Principal Investigator: *must be a faculty member*
Co-Investigators: *Names of all co-Investigators, with faculty/student status identified*

Research Consent Form

You are being asked to be a volunteer in a research study. ***(mandatory)***

- *For protocols in which experimental treatments are proposed, and/or the potential risk to the subject is high, add* "**You are encouraged to take your time in making your decision. Discuss this study with your friends and family")**

Purpose: **(*mandatory section)***
The purpose of this study is:

- *This section should provide a brief description of the background and purpose of the study. An estimate of the # of subjects expected to participate in the study should be provided. If applicable, a statement should be included regarding why the potential subject is eligible for this study (e.g., certain type of cancer).*

Procedures: ***(mandatory section)***
If you decide to be in this study, your part will involve:

- *This section requires a simple and short description of all procedures done for the purpose of the research activity.*
- *The procedures should be addressed in the order in which they occur (e.g., Screening visit, Visit #1, Visit #2 etc.). The frequency, scheduling and time commitment of each procedure and visit, as well as the study's total time commitment, should be provided.*
- *When a complicated protocol is proposed, IRBC encourages the investigator to provide this information in a table or schema format.*
- *Procedures that would be done whether or not the subject participates in the research should not be included.*
- *If blood drawing is involved, reference should be made to the amount (in teaspoons or tablespoons) of blood that is to be drawn, as well as the frequency and scheduling of the blood drawing procedure.*
- *If subjects are being randomly assigned to different groups, the consent form should reflect this randomization, and should read:* **"You will be randomly ('by chance, like flipping a coin'') assigned to one of…."**
- *An investigational drug should be referred to as an 'experimental drug'*
- *A placebo should be referred to as 'inactive substance'*
- *Any audio-or video- taping should be addressed in this section as well.*

Risks/Discomforts ***(mandatory)***
The following risks/discomforts may occur as a result of your participation in this study:

- *This section should describe the reasonably foreseeable risks and discomforts that may be expected from each of the procedures that a subject will be undergoing for research purposes. Nonphysical risks (i.e., inability to work, inability to drive) should be included as well.*
- *All risks/discomforts should be grouped according to probability of occurrence (i.e., 'rare', 'common') as well as whether or not they are temporary or permanent.*
- *If there are no anticipated risks or discomforts associated with a subject's participation, the consent form should include such a statement, i.e.*, **There are no foreseeable risks or discomforts associated with your participation in this study."**
- *If the subject will be receiving a number of drugs (experimental or standard), it is recommended that the risks should be presented for the entire regimen, rather than listing the risks for each specific drug.*
- *In studies involving experimental treatments, a statement should be added that* **'Since this is a research study, not all risks may be known at this time; there may be unforeseen risks associated with study participation'**
- *The risks associated with blood drawing should be stated as:* **"temporary pain and bruising where the needle enters the skin, and sometimes, fainting".**
- *If there are special risks to pregnant/nursing women, fetuses, and/or women of childbearing potential, these should be discussed in boldfaced print, with special instructions regarding need for effective birth control. Similar discussion for men should be included for studies in which effects on sperm are possible. IRBC requires the following boilerplate language (borrowed heavily from Duke University's IRB Website) for such instances where women of childbearing potential are included in the subject population of research involving the administration of drugs with either known or unknown risk to a fetus.*

'Being a part of this study while pregnant may expose the unborn child to significant risks that are not justified, given the purpose of the study. Therefore, pregnant women will be excluded from the study. If you are a woman who can become pregnant, a pregnancy test must be done, and must be negative before you can enter this study. Follow-up pregnancy tests may be required, and the scheduling for these are outlined in the procedures section of this form. If you are sexually active, you or your partner must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptives include (1) surgical sterilization, (2) approved hormonal contraceptives, such as birth control pills, Depo-Provera, or Lupron Depot (3) Barrier methods (such as condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). If you do become pregnant during this study, you must inform your study physician immediately.'

<u>Benefits</u> *(mandatory)*
The following benefits to you are possible as a result of being in this study:

- *This section should describe any direct <u>therapeutic</u> benefits (to the subject) or indirect benefits (to others) that may be derived from participation in the study. If*

there are no foreseeable direct benefits associated with a subject's participation, the consent form should include such a statement.

Payment to You (*mandatory-Also note that if subject pool is involved, this section should be titled 'Credit to Subjects')*

- *This section should address compensation/reimbursement (money, subject pool credits)**.***
- *IRBC requires that compensation be prorated; as such, this section should address the scheduling of prorated payment (e.g., $25 per visit, $10 per blood draw etc.)*
- *If the subject is not going to be paid, or receive credit (in the case of subject pools), the applicable statement should be included.*

Funding of the Study and/or Financial Interest of the Study Investigators (*if applicable)*

- *This section should address*
    - ***In the case of a sponsor- funded study:***
        - *Who the sponsor is (by name)*
        - *The fact that the investigator is compensated through a grant to the Research Foundation of SUNY*
        - *The schedule upon which sponsor payments are made (e.g., on a 'per enrolled subject' basis etc)*
    - ***In the case where one or more of the study investigators may directly benefit financially from the conduct or results of the study (i.e., via stocks, ownership, partnerships, etc.)***
        - A statement that one or more of the study investigators may benefit financially from the conduct or results of the study.
        - A declaration that none of these investigators will participate in the recruitment of subjects, or the subjects' consent processes.
        - A statement that such relationships between an investigator and potential financial benefit are additionally handled at the University level via a conflict of interest policy

Confidentiality (*mandatory*)

- *This section should describe the extent, if any, to which confidentiality of records that identify the subject will be maintained. Since the majority of studies propose to keep the subject's identity confidential, the following statement should be used to start this section:*

'The following procedures will be followed in an effort to keep your personal information confidential in this study: Your identity will be coded, and all data will be kept in a secured, limited access location. Your identity will not be revealed in any publication or presentation of the results of this research. However, confidentiality cannot be guaranteed; your personal information may be disclosed if required by law.'

- ***For research activities where access to medical records will be required, the following statement should be added (note that this subsection will become a distinct section in the consent form once legally-acceptable boilerplate language is drafted to satisfy the research subject privacy issues addressed in the Health Insurance Portability and Accountability Act-HIPAA)***

'In order to conduct this research, it is necessary for the investigators to have access to the information contained in your medical records.'

- *For research activities, where confidentiality of subject identity is not proposed (e.g., where subjects will be quoted by name) this section should be very clear regarding where and how the quotes will be used. Subjects should also have the opportunity to review the text in which their quotes or identity appear, to ensure proper attribution.*
- *IRBC has the right to review study and medical records. In addition, if there is Food and Drug Administration (FDA) oversight (e.g., protocol involves use of drugs, biologics or devices*), *and/or if the research is sponsored (e.g., NIH, pharmaceutical company, oncology group), then the following statement should be added (revise as applicable; SUNY-O's IRBC reference should be included regardless of FDA/sponsor oversight):*

'To ensure that this research activity is being conducted properly, SUNY State College of Optometry's Committee on Research Involving Human Subjects, {the Food and Drug Administration and the sponsor of this study, "Acme Drug Company"}, has {have} the right to review study and medical records, but confidentiality will be maintained as allowed by law'

- ***If there will be payment to subjects, the following statement should be added:***

'By accepting payment for participating in this study, certain identifying information about you may be made available to professional auditors to satisfy audit and federal reporting requirements, but confidentiality will be preserved. Please note that if you earn $600 or over in a calendar year as a research subject, you may have to pay taxes on these earnings.

- *If the study involves use of video/audio taping of the subject, include a statement specifically addressing who has access to the tapes, how they are stored, for what purposes will the tapes be used, and what happens to the tapes once the study is ended (i.e., Are they erased after all the necessary information is collected from them? Are they kept for archival purposes?).*

Costs to You (***mandatory)***

- *Describe the financial obligation of the subject as a participant in the study.*
- *If there are no foreseeable costs, this information should be specified as well.*
- *If the possible costs to the subject are high, a statement should be added encouraging the subject to contact his/her insurance company, and/or discuss the costs with the investigator* ***prior*** *to consenting to be in the study.*

Alternative Treatments (*applicable **only** if the study involves treatment[s])*

- *Describe other treatments or procedures available if the subject chooses not to participate, or if the subject withdraws from the study. The relative risks and benefits of these alternative treatments should be discussed as well.*

In Case of Injury (***applicable if the study involves the potential for injury (psychological, physical, etc.) to subject. This would include blood drawing protocols***)

- Standard text:

'If you are injured as a result of being in this study, please contact [Dr. X. Investigator at telephone # [XXX-XXXX]. The services of SUNY, State College of Optometry's University Optometric Center will be open to you in case of such injury. However, you and/or your insurance company will be responsible for payment of any resulting treatment.'

NOTE: The last sentence above may be modified accordingly in cases where the sponsoring company pays for such treatment.

Consequences of Withdrawing (***if applicable***)

- *Describe the consequences and steps to be followed if a subject decides to withdraw from the research (e.g., subject must be taken off drug slowly, must show up for a follow-up visit to check for effects, subject will not receive subject pool credit)*

Removal from Study (***if applicable***)

- *Describe the circumstances under which a subject will be removed from the study (e.g., non-compliance, bad reaction to drug)*

Subject Rights (***Mandatory as written***)

- **Your participation in this study is 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 form to keep.**
- **You do not waive any of your legal rights by signing this consent form.**

Questions about the Study or Your Rights as a Research Subject (***mandatory***)

- **If you have any questions about the study, you may contact [Dr. X. Investigator], at telephone # (631-XXX-XXXX).**

- **If you have any questions about your rights as a research subject, you may contact Dr. Mort Soroka, Committee on Research Involving Human Subjects, (212) 780-5024.**

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 be a volunteer in this study.

_____

Subject Name

Subject Signature **Date**

Signature of Person Obtaining Consent **Date**

Section 15
Consent (Permission)/Assent Requirements: Minor Subjects (less than 18 years old)

(see section 10 for additional information concerning minor subjects in research)

A. Required Format for Permission form (addressed to parent /legal guardian)

Introduction:
All permission forms MUST

- be printed on departmental letterhead,
- 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
- follow the format, including headings, given below:

Departmental Letterhead

Project Title:
Principal Investigator: *(must be a faculty member)*
Co-Investigators: *Names of all co-investigators, with faculty/student status identified*

Research Permission Form
(for Parents of Minor Subjects)

You are being asked to allow your child to be in a research study. ***(mandatory)***

- *For protocols in which experimental treatments are proposed, and/or the potential risk to the subject is high, add* "**You are encouraged to take your time in making your decision. Discuss this study with your friends and family")**

Purpose: (*mandatory section)*

The purpose of this study is:

- *This section should provide a brief description of the background and purpose of the study. An estimate of the # of subjects expected to participate in the study should be provided. If applicable, a statement should be included regarding why the potential subject is eligible for this study (e.g., certain type of cancer).*

Procedures: ***(mandatory section)***

If you decide to allow your child to be in this study, his/her part will involve:

- *This section requires a simple and short description of all procedures done for the purpose of the research activity.*
- *The procedures should be addressed in the order in which they occur (e.g., Screening visit, Visit #1, Visit #2 etc.). The frequency, scheduling and time commitment of each procedure and visit, as well as the study's total time commitment, should be provided.*
- *When a complicated protocol is proposed, IRBC encourages the investigator to provide this information in a table or schema format.*
- *Procedures that would be done whether or not the subject participates in the research should not be included.*
- *If blood drawing is involved, reference should be made to the amount (in teaspoons or tablespoons) of blood that is to be drawn, as well as the frequency and scheduling of the blood drawing procedure.*
- *If subjects are being randomly assigned to different groups, the permission form should reflect this randomization, and should read:* **"Your child will be randomly ('by chance, like flipping a coin'') assigned to one of…."**
- *An investigational drug should be referred to as an 'experimental drug'*
- *A placebo should be referred to as 'inactive substance'*
- *Any audio-or video- taping should be addressed in this section as well.*

Risks/Discomforts ***(mandatory)***

The following risks/discomforts may occur as a result of your child's participation in this study:

- *This section should describe the reasonably foreseeable risks and discomforts that may be expected from each of the procedures that a subject will be undergoing for research purposes. Nonphysical risks (i.e., inability to work, inability to drive) should be included as well.*
- *All risks/discomforts should be grouped according to probability of occurrence (i.e., 'rare', 'common') as well as whether or not they are temporary or permanent.*
- *If there are no foreseeable risks or discomforts associated with a subject's participation, the permission form should include such a statement.*

- *If the subject will be receiving a number of drugs (experimental or standard), the risks should be presented for the entire regimen, rather than listing the risks for each specific drug.*
- *In studies involving experimental treatments, a statement should be added that* **'Since this is a research study, not all risks may be known at this time; there may be unforeseen risks associated with study participation.'**
- *The risks associated with blood drawing should be stated as:* **"temporary pain and bruising where the needle enters the skin, and sometimes, fainting".**
- *If there are special risks to pregnant/nursing females, fetuses, and/or females of childbearing potential, these should be discussed in boldfaced print, with special instructions regarding need for effective birth control. Similar discussion for males should be included for studies in which effects on sperm are possible. IRBC requires the following boilerplate language (borrowed heavily from Duke University's IRB Website) for such instances where women of childbearing potential are included in the subject population of research involving the administration of drugs with either known or unknown risk to a fetus.*

'Being a part of this study while pregnant may expose the unborn child to significant risks that are not justified, given the purpose of the study. Therefore, pregnant females will be excluded from the study. If your child is female and can become pregnant, a pregnancy test must be done, and must be negative before she can enter this study. Follow-up pregnancy tests may be required, and the scheduling for these are outlined in the procedures section of this form. If your child is sexually active, her and her must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptives include (1) surgical sterilization, (2) approved hormonal contraceptives, such as birth control pills, Depo-Provera, or Lupron Depot (3) Barrier methods (such as condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). If your child becomes pregnant during this study, you must inform the study physician immediately.'

Benefits ***(mandatory)***
The following benefits to your child are possible as a result of being in this study:

- *This section should describe any direct therapeutic benefits (to the subject) or indirect benefits (to others) that may be derived from participation in the study. If there are no direct benefits associated with a subject's participation, the permission form should include such a statement.*

Payment to You/Your Child (***mandatory-Also note that if subject pool is involved, this section should be titled 'Credit to Subjects'***)

- *This section should address compensation/reimbursement (money, subject pool credits). Permission form should be clear regarding whether the parent/guardian and/or minor subject receives the remuneration.*
- *IRBC requires that compensation be prorated; as such, this section should address the scheduling of prorated payment (e.g., $25 per visit, $10 per blood draw etc.)*

- *If the subject is not going to be paid, or receive credit (in the case of subject pools), the applicable statement should be included.*

Funding of the Study and/or Financial Interest of the Study Investigators (if applicable)

- *This section should address*
    - ***In the case of a sponsor- funded study:***
        - *Who the sponsor is (by name)*
        - *The fact that the investigator is compensated through a grant to the Research Foundation of SUNY*
        - *The schedule upon which sponsor payments are made (e.g., on a 'per enrolled subject' basis etc)*
    - ***In the case where one or more of the study investigators may directly benefit financially from the conduct or results of the study (i.e., via stocks, ownership, partnerships, etc.)***
        - A statement that one or more of the study investigators may benefit financially from the conduct or results of the study.
        - A declaration that none of these investigators will participate in the recruitment of subjects, or the subjects' consent processes.
        - A statement that such relationships between an investigator and potential financial benefit are additionally handled at the University level via a conflict of interest policy

Confidentiality (*mandatory*)

- *This section should describe the extent, if any, to which confidentiality of records that identify the subject will be maintained. Since the majority of studies propose to keep the subject's identity confidential, the following statement should be used to start this section:*

'The following procedures will be followed in an effort to keep your child's personal information confidential in this study: His/her identity will be coded, and all data will be kept in a secured, limited access location. Your child's identity will not be revealed in any publication or presentation of the results of this research. However, confidentiality cannot be guaranteed; your child's personal information may be disclosed if required by law.'

- *For research activities where access to medical records will be required, the following statement should be added (**note that this subsection will become a distinct section in the consent form once legally-acceptable boilerplate language is drafted to satisfy the research subject privacy issues addressed in the Health Insurance Portability and Accountability Act-HIPAA)***

'In order to conduct this research, it is necessary for the investigators to have access to the information contained in your child's medical records.'

- *For research activities, where confidentiality of subject identity is not proposed (e.g., where subjects will be quoted by name) this section should be very clear regarding where and how the quotes will be used. Subjects should also have the opportunity to review the text in which their quotes or identity appear, to ensure proper attribution.*
- *IRBC has the right to review study and medical records. In addition, if there is Food and Drug Administration (FDA) oversight (e.g., protocol involves use of drugs, biologics or devices), and/or if the research is sponsored (e.g., NIH, pharmaceutical company, oncology group), then the following statement should be added (revise as applicable; SUNY-O's IRBC reference should be included regardless of FDA/sponsor oversight):*

'To ensure that this research activity is being conducted properly, SUNY State College of Optometry's Committee on Research Involving Human Subjects, {the Food and Drug Administration and the sponsor of this study, "Acme Drug Company"} has {have} the right to review study and medical records, but confidentiality will be maintained as allowed by law'

- *If there will be payment to subjects, the following statement should be added:*

'By accepting payment for participating in this study, certain identifying information about you may be made available to professional auditors to satisfy audit and federal reporting requirements, but confidentiality will be preserved. Please note that if you earn $600 or over in a calendar year as a research subject, you may have to pay taxes on these earnings.

- *If the study involves use of video/audio taping of the subject, include a statement specifically addressing who has access to the tapes, how they are stored, for what purposes will the tapes be used, and what happens to the tapes once the study is ended (i.e., Are they erased after all the necessary information is collected from them? Are they kept for archival purposes?).*

Costs to You (*mandatory)*

- *Describe the financial obligation of the parent as a result of allowing the child to participate in the study.*
- *If there are no costs, this information should be specified.*
- *If the possible costs to the parent are high, a statement should be added encouraging the parent to contact his/her insurance company, and/or discuss the costs with the investigator prior to permitting the child's participation in the study.*

Alternative Treatments (*applicable only if the study involves treatment[s]*)

- *Describe other treatments or procedures available if the parent chooses not to have the child participate, or if the parent withdraws the child from the study. . The relative risks and benefits of these alternative treatments should be discussed as well.*

<u>In Case of Injury</u> (*applicable if the study involves the potential for injury [psychological, physical etc.] to subject. This would include blood drawing protocols*)

- Standard text:

'If your child is injured as a result of being in this study, please contact [Dr. X. Investigator at telephone # [XXX-XXXX]. The services of SUNY-State College of Optometry's University Optometric Center will be open to him/her in case of such injury. However, you and/or your insurance company will be responsible for payment of any resulting treatment.'

NOTE: The last sentence above may be modified accordingly in cases where the sponsoring company pays for such treatment.

<u>Consequences of Withdrawing</u> (*if applicable*)

- *Describe the consequences and steps to be followed if a parent decides to withdraw the child from the research (e.g., child must be taken off drug slowly, must show up for a follow-up visit to check for effects)*

<u>Removal from Study</u> (*if applicable*)

- *Describe the circumstances under which the child will be removed as a subject from the study (e.g., non-compliance, bad reaction to drug)*

<u>Subject Rights</u> (*Mandatory as written*)

- **Your child's participation in this study is voluntary. You do not have to allow your child to be in this study if you don't want him/her to be.**
- **You have the right to change your mind and remove your child from the study at any time without giving any reason, and without penalty.**
- **Any new information that may make you change your mind about allowing your child to participate in this study will be given to you.**
- **You will get a copy of this permission form to keep.**
- **You do not waive any of your or your child's legal rights by signing this permission form.**

<u>Questions about the Study or Your Child's Rights as a Research Subject</u> (*mandatory*)

- **If you have any questions about the study, you may contact [Dr. P. Investigator], at telephone # (212-XXX-XXXX).**
- **If you have any questions about your child's rights as a research subject, you may contact Dr. Mort Soroka, Committee on Research Involving Human Subjects, (212) 780-5024**

If you sign below, it means that you have read (or have had read to you) the information given in this permission form, and you would like your child to participate in this study.

_____

Subject Name

Parental Signature	**Date**
Signature of Person Obtaining Permission	**Date**

B. Assent (and Documentation of Assent) Requirement

IRBC requires that provisions be made for obtaining the assent of children to be subjects under certain conditions (see section 10 for full details). Aside from age (usually 11-17 years old), the maturity and psychological/physical state is taken into account in determining the ability of obtaining **documented** assent. IRBC 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.
Example:

Departmental Letterhead

Project Title: The Effects of Providing Examples on Writing Assent Forms
Principal Investigator: Dr. P. Investigator.

You are being asked to be in a research study.
Purpose: The purpose of this study is to show you an example of how to write an assent form.
What Will Be Done: If you agree to be in this study, you will be asked to review this example, and then try to write your own. You will be in this study for about 10 minutes.
Costs to You: You will not have to pay anything to be in this study.
Payment to you: You won't get paid for being in this study.
Risks/Discomforts: The only risks or discomforts involved in being in this study is that you may get a paper cut, which can hurt.
Benefits: The only benefit to you as a subject in this study is that you may learn how to write better assent forms.
In Case of Injury: If you get hurt as a result of being in this study, your parents/guardian have been told what to do.
Your rights:
The fact that you are in this study will be kept a secret.
You don't have to be in this study if you don't want to be.
You can change your mind at any time and leave the study without any problem and without telling us why.

Questions:
If you have any questions about this study, you can ask your parents, or talk to the study doctor, Dr. P. Investigator, at 212 780-XXXX.

- If you want to talk to someone about whether or not you have to be in this study, or about other things about this study that you don't want to talk over with your parents or the study doctor, you can contact Dr. Mort Soroka, Committee on Research Involving Human Subjects at (212) 780-5024.

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If you sign below, it means that you have read this sheet, and you'd like to be in this study.

Name

Signature date

Section 16
Continuing Review Of IRBC-Approved Activities

A. Observation of Research by IRBC

IRBC 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. Oversight Compliance

The Office of Research Compliance has initiated a formal proactive program to oversee investigator compliance with IRB regulations. These are not 'for-cause' audits. When a protocol is chosen for review, the Principal Investigator of record will receive a questionnaire to complete regarding the protocol in question. Questions will be asked to assess procedural compliance with human subject regulations. The investigator may be contacted to provide copies of a random sampling of subject files for review. Depending on the responses provided, the review team (made up of IRB members, Research Compliance staff, and other administrators as appropriate) will decide what action must be taken, ranging from acceptance of current practice, to need for on-site inspection.

C. Renewal Procedures

See section 6 regarding general information on IRBC approval periods

IMPORTANT: It is the Principal Investigator's responsibility to maintain continued approval for his or her study. However, the Office of Research Compliance sends reminder notices as follows:

1. Renewal Notices:

- Approximately 2 months prior to the end of the approval period, the investigator will be sent a memorandum outlining the materials that must be submitted in order to renew a project for the next approval period.
- After the initial notice to renew, the investigator will receive a final notice one month later.

IRBC strongly urges that the investigator be aware of application deadlines, and review time considerations (Section 4) to ensure continued coverage of project approval. The current IRBC schedule of deadlines and meeting dates is available at:

http://www.sunyopt.edu/research/res_inst_poli.shtml

- **If continued approval has not been secured by the expiration date of the prior approval period, all research activities involving human subjects, human data or biological specimens pertaining to the study in question must be stopped immediately. The Office**

of Research Compliance must be contacted if and when the investigator wishes to reactivate the study.

2. **Required renewal materials include:**
   - **Renewal application,** requiring full completion, followed by signatures of the principal investigator, and chair of the department or departmental review committee.
   - **Publications:** Attach a reprint of any publications/abstracts derived from your study since last approval
   - **Consent/permission/assent forms:**
     If there has been accrual in the study, attach a copy of the form used to enroll a subject since the last approval date (**remove subject's name and signature to preserve confidentiality.** Leave the date intact).
     If you plan on continuing accruing subjects over the next approval period, submit a 'clean' original consent/assent form(s) for review
   - **Subject Recruitment Materials** If there will be continued recruitment of subjects, submit copies of all materials (advertisements, letters, flyers) to be used to recruit new subjects.
   - **Audit Reports**
     Attach a copy of any reports from audits/monitoring visits conducted by external organizations (e.g., FDA, HHS, NCI, sponsors) since last IRBC review.

3. **Required Number of Copies of Materials**
   - One e-mail attachment and one hard copy (signed).

As stated above, review time considerations are as outlined in section 4.

IRBC reserves the right to obtain outside verification from sponsors, collaborating investigators etc. regarding protocol status at time of continuing review.

4. **Four Renewal Limit on IRBC-Approved Activities:**

A study may only be renewed four (4) times. After such time, a complete, original application must be submitted in order for the activity to be considered for continued approval (see below for exceptions). The new submission should incorporate all amendments, revised aims, and funding sources that have become applicable over the years during which the project has been active. A complete, current protocol must be submitted at this time, as well as all consent documents to be used.

The requirement for new submission is waived if:
a) the human subject aspects of the study are now limited to data analysis,
b) enrollment has ended, subjects have complete all research-related intervention,
AND the study is now limited to long-term follow-up of subjects, OR
c) there have been no amendments to the study during the time it has been active with IRBC.

If A,B or C applies, the activity must STILL be renewed, by completing the standard renewal application WITH REQUIRED MATERIALS AS STATED IN THE APPLICATION DIRECTIONS.

D. Amendments to Approved Studies

IRBC approval for studies is contingent upon many assurances by the investigator, including the fact that s/he will:

- conduct every aspect of the project as approved by IRBC,
- promptly report any revisions or amendments to the research activity for review and approval by IRBC 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 subject)

All amendments to approved protocols must be submitted to IRBC for review and approval prior to commencement of the revised study or use of a revised consent/permission/assent form. Three copies of all materials pertaining to the amendment should be submitted for review.

Major Amendments, i.e., those involving a substantive increase in risk to the subject, are brought to full committee, with a primary reviewer assigned to present the issues in question, and start committee deliberations.

Minor Amendments, i.e., those that do NOT involve a substantive increase in risk to the subject, are reviewed via the expedited review process, which is fully described in section 2.B.

E. Adverse Event Reporting

1) Introduction:
As a IRBC-approved investigator, you are responsible for prompt reporting to the IRB of “any unanticipated problems involving risks to subjects or others…” (45CFR46.103.b (5) and 21CFR56.108(b)(1))

Why?

IRBC is responsible for initial assessment of the risk/ benefit ratio inherent in a given proposed research activity involving human subjects. During the conduct of the activity, the committee depends on the investigator to promptly inform them of any unanticipated negative effect possibly, probably or definitely related to study procedures (‘adverse event’) that may affect that ratio. As a result, IRBC may determine that the study and/or consent form needs to be updated, and/or currently enrolled subjects need to be informed of the new information to determine whether or not they wish to continue, or that the risk to subjects has changed such that the study must be stopped.

This policy only addresses reporting requirements for adverse events that are possibly, probably or definitely related to the study procedures. If such a relationship can be definitively ruled out, then the adverse event should not be reported to IRBC.

In order to assess the relationship of the event to the study procedures, the investigator must use his/her expertise along with the known risks associated with study participation. Examples of variables to consider include: a) the temporal sequence between the adverse event and the procedure/treatment and b) the probability that the event could have been caused by the subject's underlying clinical state, or other non-study related procedures that the subject's was undergoing at the time of participation in the study.

2) Reporting Requirements

Definitions for charts below:

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
Serious Event:

- **For Activities involving Drugs, biologics or devices (21CFR312.32 and 812.3)**
  A serious event, other than death or a life threatening event, is one that results in any of the following outcomes: 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 (e.g., allergic bronchospasm, convulsions, development of drug dependency)

- **For Activities NOT involving Drugs, Biologics or Devices:**
  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. If in doubt, it is best to err on the side of contacting the Office of Research Compliance and/or reporting to the IRB.

a. ALL adverse events occurring in subjects enrolled in gene therapy protocols must be reported to IRBC within 1 working day of occurrence (if STATE COLLEGE OF OPTOMETRY subject) or receipt by STATE COLLEGE OF OPTOMETRY investigator (if non-STATE COLLEGE OF OPTOMETRY subject).

b. Adverse Events Occurring in Subjects Enrolled through State College of Optometry

	Death/ Life Threatening	Other Serious (not life threatening)	Non-Serious
Expected			

Unexpected

c. Adverse Events Occurring in Subjects Enrolled through NON-STATE COLLEGE OF OPTOMETRY sites

	Death/ Life Threatening	Other Serious * (not life threatening)	Non-serious
Expected	Report to IRBC within **5 working days** of receipt of report by SBU Investigator	Report to IRBC at time of continuing review	no report required
Unexpected	Report to IRBC within **1 working day** of receipt of report by SBU Investigator	Report to IRBC within **5 working days** of receipt of report by SBU Investigator	Report to IRBC at time of continuing review

d) Additional Investigator Reporting Requirements

Investigators are responsible for complete compliance with FDA and sponsor adverse event reporting requirements, where applicable.

3) Mechanism of Reporting to IRBC:

For each Adverse Event where 1 or 5 working day reporting is required, an STATE COLLEGE OF OPTOMETRY Adverse Event Reporting Form must be fully completed by the Principal Investigator of the study. The Principal Investigator must sign the form, unless s/he has submitted to the Office of Research Compliance a statement that a) names a designee to complete and sign on PI's behalf, and b) provides assurance that the PI retains full responsibility for the required reporting process, as outlined in State College of Optometry's Policy on Reporting Adverse Events.

The AE Reporting Form may be completed and submitted by a co-investigator listed on the relevant IRBC-approved study only if the Principal Investigator or his/her designee is physical absent from the University during a period of time within which mandatory reporting of the adverse event is required.

NOTE: If the event is serious and unexpected, the risks section of the consent form may need to be revised to include the possibility and likelihood of the event. If subjects are currently enrolled in the study, a consent addendum may need to

be drafted, using the format provided in the IRBC Guidelines for Investigators. A revised consent form/consent addendum may be submitted at the time of AE reporting, if the PI believes such action is warranted prior to IRBC review.

The Principal Investigator will be expected to provide a summary and assessment of all other adverse events at the time of continuing review, via accurate completion of the appropriate sections of the IRBC continuing review application

4) IRBC Review of Adverse Event Forms

- Any report above that is required within 1 working day will be forwarded immediately to the appropriate IRBC chair for review and course of action.
- Any report that is required within 5 working days will be forwarded to an IRB member for review and for presentation at the next convened meeting of IRBC. If the member feels that a more immediate action is required, s/he will forward the report to the IRBC chair for review and course of action.
- All other reports will be reviewed at the time of continuing review**.**

IRBC will forward to the Institutional Official for Human Subject Protections (I.O.) any reports of injuries or other unanticipated problems involving risks to subjects or others. Federal sponsors will be promptly notified of such problems by the I.O., as required under 45CFR46.103 (b) (5). OHRP will be notified by the I.O., where appropriate.

F. Amendment- or Adverse Event- related changes to consent/permission/assent forms

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 IRBC-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):

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 3 tsp. of blood will be taken at your 4th visit….OR….it has been determined that the experimental drug used in this study can cause…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 your original consent form (attached) 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 the study, you may contact [Dr. X. Investigator], at telephone # (212-XXX-XXXX).
If you have any questions about your rights as a research subject, you may contact Dr. Mort Soroka, Committee on Research Involving Human Subjects, (212) 780-5024.

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

Section 17
Training of Investigators in the Protection of Human Subjects in Research Activities

A. Training Policy
All individuals who are involved in human subjects research, and who will work directly with subjects, or with data or biological specimens derived from subjects or patients, are required 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, and IRB approval for pending projects will be withheld until such time as all individuals are identified, and training verified, by the Office of the Associate Dean for Graduate Studies and Research (Associate Dean for Research).

The Associate Dean for Research has determined that this requirement may be met by successful completion of the CITI (Collaborative IRB Training Initiative) Web-based training program.

B. What does 'successful completion' mean?
Successful completion means that the individual scores a 70% or above on the examination at the end of the lecture, or a composite score of 70% on all the quizzes that must be taken at the end of each CITI module.

CERTIFICATION IS VALID FOR THREE (3) YEARS. See section G below for details.

C. What is the CITI Program?
The current CITI Program consists of 9 modules with quizzes, all of which are specified on the CITI site. There are an additional 4 modules that are required at this institution if you are active in those research areas.

ALL RESEARCHERS MUST FOLLOW DIRECTIONS CAREFULLY, SUCH THAT THEY REVIEW AND DOWNLOAD REQUIRED STATE COLLEGE OF OPTOMETRY POLICIES AS DIRECTED, AND COMPLETE A CERTIFICATE OF COMPLETION. THIS WILL ALERT THE OFFICE OF RESEARCH COMPLIANCE THAT YOU HAVE FINISHED CITI.

One of the major benefits of the CITI program is that you can complete the coursework at your leisure. You can complete a few modules and their associated quizzes, and come back at a later time to complete a few more, etc.

Who can use the CITI program?

STATE COLLEGE OF OPTOMETRY offers access to the CITI program to all STATE COLLEGE OF OPTOMETRY faculty, staff, or students. Non-STATE COLLEGE OF

OPTOMETRY investigators can use the CITI program if they are on file with IRBC as an investigator on an IRB application (approved or pending).

Unauthorized use of the CITI program is prohibited.

F. CITI Registration

You may register for CITI by proceeding to the following registration webpage: http://www.miami.edu/citireg/

Within 24 hours (weekends and holidays excluded), you will receive an e-mail from sunyreg@jaguar.ir.miami.edu with your username and password, as well as instructions on how to access the CITI site to begin your training.

G. What if you fail?
If you fail the CITI program (< 70% correct), you will be asked to re-take the CITI program.

H. Continuing Education
Once you have completed the CITI program, your username and password will still be valid for you to re-enter any of the modules to access links, and to review information whenever you need to. The 'hot topics' module is a site where you can review information on important issues impacting researchers and research involving human subjects.

I. Re-certification

Re-certification is required every 3 years for STATE COLLEGE OF OPTOMETRY researchers, and is accomplished via a web-based program available through CITI.

Section 18
Data/Tissue Registries

Mandated Registries: defined as registries that are required by a state or federal governmental agency. The IRB of STATE COLLEGE OF OPTOMETRY has determined that submission of patient data/biological specimens to these registries are not under their jurisdiction, and specific research consent is not required. However, they do have jurisdiction over any proposed research use of identifiable and primary (i.e., not aggregate/anonymous) data/specimens from such mandated registries. Further the IRB urge that, given the impact on HIPAA in these matters, the UH Consent form should be modified to contain a statement that such types of submissions may be possible once an individual formally becomes a patient at STATE COLLEGE OF OPTOMETRY.

Non-mandated Registries: defined as registries not required by a state or federal governmental agency. IRB approval and prior patient consent are required in order for an

investigator to submit data/specimens to such entities. Payments made to investigators as a result of submission of patient data/specimens must be disclosed in the consent document. For any such activity discovered as having been going on before IRB approval is obtained, the registry in question will be contacted by the Office of Research Compliance for information on how the data/specimens are stored. If anonymously stored, IRB will confirm that a waiver of consent from patients can be granted, in accordance w/ federally mandated criteria. If information is stored w/identifiers, patients must be contacted for consent to use their data. All data of patients lost to follow-up, or of patients who refuse to sign the consent, must be removed from the registry. Any financial repercussions resulting from having data removed from a non-mandated registry remains the Principal Investigator's responsibility.

Section 19
Biological Specimens in Clinical (including Genetic) Research

A. Introduction

This section summarizes the findings of a special subcommittee, formed at the request of the Committee on Research Involving Human Subjects at SUNY, Stony Brook, charged with the responsibility of drafting procedures and policy to guide the ethical use of human biological specimens in research activities. The subcommittee tried to keep two critical factors in balance: The rights and welfare of the person from whom the specimen was/will be obtained, and the need not to impede the research activities conducted at SUNY Stony Brook. Their recommendations are accepted by SUNY, State College of Optometry.

One important issue addressed by the subcommittee concerned the types of information that could be obtained from research on biological specimens. Most notably, the investigator and IRBC need to evaluate risks that are not necessarily physical, but rather, are of a psychosocial nature. **For example, a risk to the subject could be one of a possible breach in confidentiality, whereby insurance companies, employers etc. might gain access to sensitive information pertaining to the person's current (e.g., HIV) or future (e.g., presence of a gene for breast cancer) health status.** If the purpose of the research is genetic in nature, the results could affect entire families. The subcommittee, therefore, endorsed securing tissues in an anonymous fashion to the extent that it is practical with respect to the aims of the research activity.

Another issue that was raised was the consideration of a study that proposes *secondary* use of biological specimens, i.e., use of samples collected for a previously conducted study. When this situation arises, IRBC will make an assessment regarding whether or not the consent (if required; see charts below) that was obtained for the first study is applicable to the second. If the purpose of the new study differs significantly from the purposes stated in the original study, and the specimens are identifiable, obtaining new consent will be required. The subcommittee, therefore, strongly recommended obtaining the initial consent for research with as broad a stated purpose as possible.

The guidelines below distinguish between genetic vs. non-genetic research, prospective vs. retrospective specimen collections, clinically vs. research-related collections, and anonymous

vs. coded/labeled specimens. Each implies a varying amount of possible risk to the subject from whom the specimen is obtained. The charts below acknowledge the degree of possible risk inherent in each scenario, via the assessments of the consent requirement and applicable IRB review category. Section 18 should be reviewed for IRBC' specific policy on biological specimen registries. The subcommittee wishes to acknowledge that this section is based, in part, on the policies and procedures provided by University of Kentucky and Children's Hospital (Boston) at the PRIMR conference December 8-9, 1997 (Boston MA), and the IRB Guidebook (OPRR 1993).

Please note that, at the time of this writing, many of the issues covered in these guidelines (e.g., tissue ownership) are in a state of legal flux at the state and federal levels. These guidelines will be updated as relevant laws and regulations are passed.

B. Definitions

Anonymous Samples: specimens lacking any code or identifier that would allow a link back to the subject who provided it.

Exempt Review Procedure: see section II.A.

Expedited Review Procedure: see section II.B.

Full Review Procedure: Involves review by IRBC at a convened meeting. The schedule of meetings is available from the Office of Research Compliance.

Genetic Research: any research involving the analysis of human DNA and chromosomes as well as biochemical analysis of proteins and metabolites when the intent of the research is to collect and evaluate information about heritable disease and/or characteristics within a family.

Identifiable/Coded Samples: specimens that can be linked back to the subject who provided them.

Prospective Collection: specimens do not exist 'on the shelf' when request is made to IRBC for approval.

Retrospective Collections: proposed research involves using specimens that already exist, i.e., already collected and are 'on the shelf', stored or frozen at time of protocol submission to IRBC:

Third Party: As referenced below, means that the tissue is not obtained from the human subject directly, but via another source, e.g., tissue bank or registry, Department of Pathology etc. The third party may have the tissue coded with respect to subject identity, but the investigator receives the tissue in an anonymous manner, i.e., no way to link the subject's identity to the tissue once it is in the investigator's hands. Third parties should require proof of IRBC approval prior to releasing biological specimens to the investigator.

Waiver of obtaining consent, where indicated below, can be made by IRBC if all of the following conditions are met:

- Research is no more than minimal risk
- It is not practical to conduct the research without the waiver
- Waiver would not adversely affect the subject's rights/welfare
- Pertinent information is provided to subjects later, if appropriate (note: this criterion usually does not apply to research using biological materials.

C. Consent/Review Guidelines

Information contained within the following charts is based on the assumption that the only procedure involving human subjects is the collection of biological specimens. Involvement of other procedures may place the activity in a different (higher) review category, and may require consent of the subject where none is required below. The investigator must consult Sections 12, 13, 14 and 15 of this handbook for full detail concerning the consent process, mandated elements of informed consent etc

1. Retrospective Collection: Genetic Research

	Consent Required?	What type of IRBC Review?
Anonymous	NO	EXPEDITED
Identifiable	YES (WAIVED IF 3RD PARTY)	FULL (EXPEDITED IF 3RD PARTY)

2. Retrospective Collection: Non-Genetic Research

	Consent Required?	What type of IRBC Review?
Anonymous	NO	EXEMPT
Identifiable	YES (WAIVED IF 3RD PARTY)	EXPEDITED (EXEMPT IF 3RD PARTY)

3. Prospective Collection of Human Biological Specimens

a. **Collection of biological specimens via procedures performed specifically for research, OR collection of extra biological specimens during a clinically indicated procedure**

1. Genetic Research

	Consent Required?	What type of IRBC Review?
Anonymous	YES	EXPEDITED or FULL*
Identifiable	YES	FULL

*Review category depends on procedure to be performed; for e.g., most blood drawing protocols qualify for expedited review. Obtaining an additional biopsy requires review by the full committee.

2. Non-Genetic Research

	Consent Required?	What type of IRBC Review?
Anonymous	YES	EXPEDITED OR FULL*
Identifiable	YES	EXPEDITED OR FULL*

*Review category depends on procedure to be performed; for e.g., most blood drawing protocols qualify for expedited review. Obtaining an additional biopsy requires review by the full committee.

b. **Collection of biological specimens obtained from future discarded clinical samples**:

1. **Genetic**

	Consent Required?	What type of IRBC Review?
Anonymous	NO	EXPEDITED
Identifiable	YES (waived if 3rd party)	FULL

2. **Non-Genetic**

	Consent Required?	What type of IRBC Review?
Anonymous	NO	EXEMPT
Identifiable	MAYBE* (waived if 3rd party)	EXPEDITED OR FULL* *

*Can request waiver; determination will also be based on purpose of the research
**Depends on purpose of research

D. Points to Be Addressed in the Protocol and Consent Form When Proposing Research on Biological Specimens (including Tissue Banking for Future, Unspecified Research)

Informed consent must be obtained for certain research involving biological specimens (see prior section for specifics), and for the collection of biological specimens with the purpose of being banked for future, currently unspecified research. The informed consent document should include all the federally mandated elements of informed consent, written in accordance with section(s) 14 and/or 15 of this handbook and should also address the following issues, when applicable:

1. General Issues

a. If the banking of biological specimens is proposed within the context of clinical care, a distinct consent form for the tissue procurement procedure should be used, separated from the consent for the clinical procedure. It must be made clear to potential subjects that their refusal to consent for the research use of biological materials will in no way affect the quality of their clinical care.

b. If the banking of biological specimens is proposed within the context of a larger research study, the following issues can be addressed within the main research consent form, but the actual request for consent to bank the tissue should be separated out from the request to consent for the main study.

This can be achieved by adding yes/no statements right before the signature lines of the main consent: For example:

Do you agree to allow use of extra blood obtained from this study/extra tumor from your surgery for use in future research, the purposes of which are unknown at this time?

Do you agree to allow someone to contact you in the future to ask you questions about your health or to ask you to participate in more research?

c. At the time of the proposed activity, is it the intent of the investigator, or the company collaborator/sponsor to produce a commercially valuable product? If yes, disclose, in the consent form, whether or not the subject or his/her heirs will receive a portion of the profits. Note that consent forms cannot contain language through which the subject is made to waive, or appear to waive, any of his/her legal rights.

d. What happens to the specimen(s), and the data derived thereof, if the subject decides to withdraw from the study? Is the tissue removed from the study analysis or from the tissue bank? What about cell lines that have been generated?

e. How long will the biological specimen be kept?

If the specimen is anonymous (or is rendered anonymous by a third party releasing the specimen) it is acceptable to indicate, in the consent form, that the specimen will be kept for an indefinite amount of time.

If the specimen is identifiable, there are legal constraints on the time limit for storage, and specific consent must be obtained from the subject to hold the specimen for a longer period of time. Therefore, IRBC recommends that the consent document specifically state that specimens will be kept indefinitely.

f. Is there involvement of vulnerable populations proposed?

Minors

-In genetic studies, these subjects must be considered so as to prevent pressure by family members and the potential for harm that may result from disclosure of genetic information.

-Parent must sign a permission form for the banking of a minor's biological specimen.

-review sections 10 and 15 for additional discussion of involvement of minors in research activities.

Cognitively Impaired Individuals:

-Studies on the genetic basis of, e.g., Alzheimer's disease, bring into consideration the ability of the patient to give consent. Review section 13 for full discussion capacity to consent issues, acceptable surrogate signatories, acceptable categories of research etc.

g. When appropriate to the research, consent form should give subjects the option of stating their willingness to be re-contacted.

2. Confidentiality Issues

a. Where is the physical site for holding the biological specimens? On or off-campus? Individual investigator tissue bank?

b. What information will be revealed to whom (subject, subject's family, subject's doctor, employer, insurer, entered into medical record?), and under what circumstances? What information may subjects potentially learn (and NOT learn), both about themselves and others?

c. If genetic research is proposed, subjects should be informed that they have the right to NOT receive genetic information about themselves. (A possible exception involves circumstances where early treatment of a genetically linked disease could improve the subject's prognosis. The consent process should discuss this issue in detail). To the extent possible, persons undergoing genetic screening should be asked to consent in advance to the disclosure of important genetic information to relatives.

d. If results of tests done on the biological specimen(s) are to be provided to the subjects, IRBC requires that such disclosure should occur only when all of the following apply:

- The findings are scientifically valid and confirmed,
- The findings have significant implications for the subject's health concerns, **and**
- A course of action to ameliorate or treat these concerns is readily available. (this can be considered as a potential direct benefit to participation)

The protocol should describe anticipated research findings and circumstances that might lead to a decision to disclose the findings to a subject, as well as a plan for how to manage such a disclosure.

IRBC requires that any protocol proposing disclosure of genetic information to subjects must include counseling of the subject by trained genetic counselors *prior to the subject consenting to participate in the research activity.* This required procedure must be addressed in the procedures section of the consent form, as well as in the costs section (i.e., who will pay for the counseling?)

e. It results of tests are **NOT** to be provided to the subjects, explain why (e.g., the research nature of the activity etc.)

f. Will the patient's medical record (MR) be reviewed, with data linked to the specimen? (Procedures section of the consent form should be sure to request access to the medical record).

g. Who will have access to the samples, and for what purposes?

- Inform subjects if other investigators will be given access to samples (e.g., via a Tissue Bank arrangement). Explain how the patient's identity will be kept confidential, specifying if tissue and/or MR data released to other investigators will be linked with personal information (e.g., the patient's name or other personal identifiers) if the tissue/data are released to investigators using the Tissue Bank. Note that if personal identifiers will be attached to these tissue/data, specific consent from the subject will need to be obtained.

- If a new study proposes secondary use of biological specimens, i.e., use of samples collected for a previously conducted study, an assessment will be made by IRBC regarding whether or not the consent that was obtained for the first study is applicable to the second. If the purpose of the new study differs significantly from the purposes stated in the original study, and the specimens are identifiable, obtaining new consent will be required.
- IRBC therefore recommends obtaining the initial consent for research with as broad a stated purpose as possible.

h. Given the study aims and risks, should the investigator obtain a study-specific Certificate of Confidentiality from the NIH (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/certconpriv.htm)

3. Risk Issues

a. What are the non-physical risks that may result from the subject learning about his/her health status (e.g. HIV), or genetic status with respect to a certain disease? These risks include, e.g., questions of paternity, discovery of disease states other than those under study, anxiety, confusion, damage to familial relationships, compromise to the subjects' insurability and employment opportunities. In addition, what is the impact of learning the results from a test if no effective therapy exists? Is psychological stress possible for family members?

Provisions for counseling should be made available to the subject in cases where there are potential psychosocial effects of participation (Costs section of the consent form should address who will pay for such counseling)

b. What actions increase the risk of a breach of confidentiality (e.g., submitting insurance claim forms for reimbursement of genetic counseling costs)?

c. Unknown risks: subjects should be informed that there may be risks that are unknown at the time that they give consent.

Section 20
Exemptions from IRBC Approval Requirement

The only activity that is exempt from *prior* review and approval from IRBC involves the emergency use of an experimental drug (i.e., not approved by the Food and Drug Administration).

Emergency use is defined as the use of an experimental drug on a human subject in a **life-threatening** situation in which:

* there is no standard acceptable treatment available
*in which there is not sufficient time to obtain IRBC approval.

A. The emergency use must be reported to IRBC within 5 working days, with chair endorsement, and should include:

- patient history,
- justification for the emergency use
- department chair endorsement
- consent form (see subsection B, below), and
- investigational drug brochure and/or protocol (generally available from the pharmaceutical company).

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

B. 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:

- the human subject is confronted by a life-threatening situation necessitating the use of the test article
- informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent form the subject
- time is not sufficient to obtain consent from the subject's legal representative, AND
- no alternative method of approved of 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 IRBC is still required within the 5 working days.

C. The IRBC should be contacted for further information concerning the emergency use of investigational drugs as well as the emergency use of investigational devices (IND, IDE requirements etc.).

Section 21
IRBC Records

The Office of the Associate Dean for Research maintains the following IRBC records:

A. Current list of IRBC membership and qualifications

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

C. All materials submitted to the committee for initial and continued review of each study including: IRBC applications, protocol, submitted and final consent forms, adverse reaction reports, proposed amendments, progress reports, and all correspondence generated between the committee, the investigators, and, where applicable, sponsoring agencies. This information is retained for a period of three years following the inactivation of a project.

Section 22
Violations of IRBC Policies

IRBC 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 Research Compliance and/or IRBC that indicates that the rights and/or welfare of human subjects are at risk.

Reports of violations of this policy will be brought before IRBC at a convened meeting. IRBC will make a determination regarding the need for additional information/further investigation or need for immediate action. The affected Chair and Dean will be copied on all correspondence between the committee and the involved parties. Upon determination that a violation of this policy has occurred, possible sanctions considered by IRBC may include, for example, requiring that the activity in question be suspended (temporarily or permanently), and/or a establishment of a corrective action plan involving close oversight of investigator and project activities, suspension of an investigator from human subjects research etc.

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

In accordance with our Federal Wide Assurance, the following violations will be reported by the Institutional Official to the VP for Academic Affairs, the President of the College, OHRP, and affected sponsor(s) where applicable:

a) any unanticipated problems involving risks to subjects or others,

b) any serious or continuing noncompliance with 45CFR46 or the determinations of the IRB, and

c) any suspension or termination of IRB approval.

If IRBC determines that the violation involves possible scholarly or scientific misconduct, the Vice President for Research will be notified, via the Institutional Official, 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 Research Compliance and/or IRBC regarding human will be held confidential, to the extent allowed by law.

UPDATED: October-2002

RESEARCH INVOLVING HUMAN SUBJECTS P 202R

The use of human subjects in research is governed by laws and regulations set forth at the campus, State and Federal levels. The University operates under a Federalwide Assurance, FWA# 000001460. The faculty, staff and students of the University are mandated to comply with these laws and regulations.

This policy 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.

The Institutional Review Board Committee (IRBC) are the Institutional Review Boards for the University, as required by:

1. The Office for Human Research Protections (OHRP: Department of Health and Human Services)
2. The Food and Drug Administration
3. The State of New York

The purpose of IRBC review is to assure protection of the rights and welfare of human subjects in research. These rights include ensuring that the subject has the opportunity to voluntarily give informed consent.

All investigators who conduct research directly with human subjects, or indirectly via data or biological specimens derived therefrom, must undergo training on the protection of human subjects in research activities. This requirement is independent of funding status. The campus has implemented a program to meet this requirement. The program is coordinated by the Associate Dean for Graduate Studies and Research. Determination of applicable personnel, and responsibility for arranging such training, lies with the principal investigators.

Violations:

IRBC 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 Research Compliance and/or IRBC that indicates that the rights and/or welfare of human subjects are at risk.

Reports of violations of this policy will be brought before IRBC at a convened meeting. IRBC will make a determination regarding the need for additional information/further investigation or need for immediate action. The affected Chair and Dean will be copied on all correspondence between the committee and the involved parties. Upon determination that a violation of this policy has occurred, possible sanctions considered by IRBC may include, for example, requiring that the activity in question be suspended (temporarily or permanently), and/or a establishment of a corrective action plan involving close oversight of investigator and project activities, suspension of an investigator from human subjects research etc.

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

PROCEDURE: APPLYING FOR APPROVAL FOR RESEARCH INVOLVING HUMAN SUBJECTS

1. All research involving human subjects conducted, on the State College of Optometry campus, or under the auspices of the University, the Research Foundation of SUNY, or any campus-related organization, must be reviewed and approved by IRBC prior to commencement of the research activity.
Materials submitted for review should include the current "Application For Approval for Research involving Human Subjects, " a detailed protocol outlining all experimental procedures including anticipated risks and benefits to the subject, and consent forms (in accordance with 45 CFR 46 [DHHS] and, when applicable, 21 CFR 50 [FDA]). The requisite number of copies of the application and supporting documents (as fully detailed in the current version of the IRBC Guidelines) must be endorsed by the department chair or unit head and should be submitted to the Office of Research Compliance. Investigators will be notified in writing of the outcome of IRBC' review.
2. Applications for research involving human subjects which use University Optometric Center patients or facilities may require additional forms
3. Approved research must be renewed at least once annually. Renewal forms are sent to the principal investigator approximately 3 months prior to the end of the approval period. If the investigator does not secure continued approval by the time the prior approval period lapses, all human subject activities associated with the project must stop immediately until approval is obtained.
4. Unanticipated problems involving risks to subjects, adverse events or other problems must be reported promptly to IRBC for evaluation.
5. Any revisions or amendments to the approved research activity must be submitted to IRBC prior to implementing the new activity in order to determine the need for additional committee review. The only exception to this requirement is a protocol revision that must be implemented immediately to protect subject safety.
6. Full compliance with the policy/procedure handbook (WEBSITE) is required of all investigators who have the privilege of doing research involving human subjects.

INQUIRIES/REQUESTS:

Office of Associate Dean for Research
SUNY, State College of Optometry
33 West 42nd St., suite 1542
New York 10036

Phone: (212) 780-4986 Fax: (212) 780-5137
Email: jfeldman@sunyopt.edu

RELATED FORMS:
Application for Approval for Human Subjects Research
Application for Continued Approval for Human Subjects Research

RELATED DOCUMENTS:
DHHS: Code of Federal Regulations, Title 45 Part 46: Protection of Human Subjects
FDA: Code of Federal Regulations, Title 21 Parts 50 (Informed Consent), 56 (IRB's), 312 (Investigational New Drugs), 812 (Investigational Device Exemptions)
The Belmont Report: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"
SUNY-State College of Optometry: Guidelines for Research Involving Human Subjects - IRBC
Compliance Web site at: http://www.sunyopt.edu
Appropriate Articles of the NYS Public Health Law

SUNY Memo to Presidents, vol.81, No. 10 "Assurances of Compliance with Human Subjects Research Regulations"