Human Research Protection Program (HRPP) Policies and Procedures

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1. College Research Mission

1.1 Overview
The State University of New York College of Optometry (College) fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for or participating in research conducted by or under the auspices of the College. In the review and conduct of research, actions by the College will be guided by the principles set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979). Actions of the College will conform to all applicable federal, state, and local laws and regulations. In order to fulfill this policy, the College has established a human research protection program (HRPP) as described in this document.

1.2 Ethical Principles
The College is committed to conducting research with the highest regard for the welfare of human subjects. It upholds and adheres to the principles of *The Belmont Report*. These principles include:

- **Respect for Persons**, which is ensured by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations.
- **Beneficence**, which is ensured by maximizing possible benefits and minimizing possible risks to all human subjects.
- **Justice**, which is the equitable selection of subjects.

The State College of Optometry HRPP, in partnership with its research community, delineates all policies and procedures for ensuring the ethical and equitable treatment of all human subjects in research conducted under its auspices.

1.3 Regulatory Compliance
The HRPP is responsible for ensuring compliance with federal regulations, state laws, and institutional policies. All human subject research at the College is conducted in accordance with the policies and regulations found in the Common Rule and 21 Code of Federal Regulations (CFR) 50 and 56.

The College voluntarily applies the International Conference on Harmonization Good Clinical Practices Guidelines (ICH-GCP) to certain types of human subject research conducted under its
HRPP. In general, the College requires that its investigators comply with ICH-GCP guidelines when required by a sponsor, and only to the extent that they are compatible with FDA and DHHS regulations. The Institutional Research Board (IRB) of the College operates in compliance with Sections 3 and 5.11 of the ICH-GCP.

The College 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 the Directives 45CFR46, 21CFR50 and 21CFR56 (for clinical research activities regulated by the FDA). Research funded by the Department of Defense (DoD) is reviewed and conducted in compliance with 32 CFR 219, DoD Directives 3216.02, 3210.7, 6200.2, and 10 USC 980. The College has a DoD addendum to its FWA, which is signed by the Institutional Official for Human Subject Research on behalf of the Institution.

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 College to cover all research activities involving human subjects, regardless of source of funding.

1.4 HRPP Organization

The Associate Dean for Graduate Studies and Research is the official with ultimate responsibility to ensure implementation and maintenance of the HRPP and serves as the Institutional Official for Human Research (IO). The office of the Associate Dean is the Graduate Center for Vision Research (GCVR), which includes administrative staff for all research-related matters and bodies, including the IRB and the Human Research Compliance Committee (HRCC). The GCVR acts on behalf of the College when providing assurance of human subject research approval to sponsoring agencies or when dealing with regulatory agencies.

The Associate Dean is responsible for:

- Management and evaluation of all policies and procedures of the HRPP.
- Oversight of the IRB, HRCC, as well as all research investigators at the College, ensuring that all policies, procedures, and regulations are maintained and that all research is conducted with appropriate ethical standards and applicable regulations.
- Providing guidance and assistance to investigators at the College in terms of education and implementations of all policies and procedures of the HRPP.
- Implementing necessary improvements to the HRPP as a result of evaluations carried out by administration or faculty.
- Developing training requirements for investigators, board members, investigators,
and their staff and ensuring that training is carried out on a timely basis.

- Ensuring that sufficient resources are available to committees and bodies dealing with HRPP maintenance, review, and compliance.

The Associate Dean acts as the Institutional Official for the Research Foundation (RF) for the State University of New York (SUNY). The RF is the state governing body that supports research and discovery at SUNY campuses through administration of sponsored projects. The Associate Dean reports to the College President, the Vice-President and Dean of Academic Affairs, and other school officials on key matters regarding research at the College.

The Sponsored Research Officer (SRO) maintains an office in the GCVR and reports directly to the Associate Dean. The SRO responsibilities include:

- Oversight of all research activities at the College, including projects involving human subjects.
- Providing assistance to researchers at the College in applying for research funding and post-award implementation and education of the policies and procedures of the HRPP. The SRO coordinates with the Office for Sponsored Research in this capacity.
- Assisting the Chairman of the IRB in coordinating that body's function and serving as a non-voting member.
- Ensuring that all human research at the College complies with the policies and procedures of the HRPP. In this capacity the SRO acts as the chairperson of the HRCC. The SRO is responsible for regular monitoring of IRB activities and investigator compliance and conducting investigations of alleged non-compliance.
- Assisting the Director of the Clinical Vision Research Center (CVRC) and the Clinical Research Manager in coordinating human research and ensuring that activities in the CVRC comply with the policies and procedures of the HRPP.
- Serving as Chair of the HRCC.

The Sponsored Research Manager (SRM) directs the Office for Sponsored Research and reports directly to the Associate Dean. The SRM is responsible for ensuring that all sponsored research applications conform to sponsor and College requirements, including proposed budgets. The SRM is responsible for submission of all applications and, if awarded, interacts with the SUNY RF to set up accounts and oversees expenditures and encumbrances.

The Director of the Clinical Vision Research Center (CVRC) is responsible for all research carried out at the center. The Director ensures that all activities follow Good Clinical Practice and adhere to all policies and procedures of the College HRPP. The CVRC director interacts extensively with the SRO and reports directly to the Associate Dean.

The Clinical Research Manager (CRM) of the CVRC oversees all day-to-day operations of the center.
The manager maintains up-to-date records of licensure, regulatory documents, and subject consent forms. The CRM reports directly to the Director of the CVRC.

The Director of the Institutional Review Board (IRB) is responsible for overseeing all aspects of the board’s responsibilities, which include:

- Determining what research merits an IRB review.
- Ensuring that all research protocols comply with federal, state, and College HRPP policies and procedures.
- Ensuring that all investigators and staff involved in human research have current and complete training in the protection of subjects. The Director shall conduct an orientation for new IRB members during which training and relevant materials are provided (e.g., Belmont Report, federal regulations, College HRPP policies, IRB guidelines), which detail committee function and procedures.

The IRB Director interacts extensively with the SRO and reports directly to the Associate Dean for Graduate Studies and Research. The Associate Dean attends policy or recommended IRB meetings and is kept apprised of board actions via receipt of all board minutes. The Associate Dean is consulted regularly on matters pertaining to human subject protections and, through the administrative staff of the GCVR, regularly updates IRB policies and procedures with current and/or new relevant federal or state regulations. The Associate Dean or his/her staff serves as liaisons between the research investigators and the IRB. The Director of the IRB or the Associate Dean routinely circulates important correspondence pertaining to research involving human subjects to College researchers. The IRB director and the Associate Dean may meet with Chairs, their administrative assistants, and their faculty to discuss IRB policies and procedures, and federal regulations that govern clinical research.

1.5 IRB Independence

The Institutional Review Board (IRB) is the only designated reviewing body for human research at the College (see Chapter 2 below). The IRB is responsible for reviewing the scholarly validity of proposed research and ethical concerns related to risk/benefit analysis. It 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. It ensures that all human research protocols adhere to government guidelines and the College HRPP. In undertaking these responsibilities the IRB acts as an autonomous body whose actions are independent of the College administration. The makeup of IRB membership is in accordance with Federal Policy.
1.6 Availability of HRPP Policies and Procedures
The HRPP policies and procedures are available online on the College website to all sponsors, researchers, research staff, and research participants. In addition, the IRB Policies and Procedures Handbook for Investigators Handbook is available found online on IRBNet, based in part on OHRP’s “written institutional review board procedures” (http://ohrp.osophs.dhhs.gov/g-topics.htm) as a further elaboration of the College HRPP. The HRPP policies and procedures available online apply to all College faculty, staff, and students using College facilities, the facilities of another institution, or any other off-campus site. The policies and procedures also apply to visitors and users of the campus or off-campus College facilities.

1.7 HRPP Education and Training
The College is committed to providing on-going education and training for investigators and members of their research teams related to ethical concerns and regulatory and institutional requirements for the protection of human subjects. All individuals who are involved in human research, whether they work directly with subjects or with data or biological specimens derived from subjects, are required to be trained in the protection of human subjects in research activities. Until all such individuals are trained and verified by the GCVR staff, IRB approval for pending projects will be withheld. Identification of untrained personnel on ongoing IRB-approved projects will result in immediate suspension until appropriate training is conducted and verified.

The required training can be met by successful completion of the CITI (Collaborative IRB Training Initiative) web-based training program. The College offers free access to the CITI program to all College faculty, staff, and students. Collaborative investigators who are not College employees can also obtain free access to the CITI program if they are listed as an investigator on any research project application to the College IRB, whether pending or approved. Unauthorized use of the CITI program is prohibited.

Investigators can register for CITI certification by proceeding to the webpage: http://www.miami.edu/citireg/. The current CITI Program consists of 9 required basic learning modules and 4 additional modules that are also required dependent on the type of research; this is specified on the CITI site. All researchers must review and download the required modules, which present federal, state, and local research guidelines, as well as current College HRPP policies. Each of the modules has a quiz to test comprehension of content. To successfully complete the CITI training an individual must attain a composite score of at least 70%. The CITI program can be repeated in the case of failure (< 70% correct). The GCVR office will be alerted when an investigator successfully completes the CITI training. Re-certification is required every 3 years for College researchers through the web-based CITI program.

Once the CITI program is completed, an investigator retains access to the modules to review material as needed. There are 'hot topics' modules on the CITI site that investigators are advised to
visit periodically to review information on important issues impacting researchers and research involving human subjects. The GCVR staff reviews these modules on a regular basis and informs investigators when important topics are available for review.

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

The basic ethical principles that underlie the Federal Policy are summarized in The Belmont Report. These regulations, which specifically cover research funded by the National Institutes of Health, have been adopted by the College to cover all research activities involving human subjects, regardless of the funding source. The IRB operates in compliance with sections 3 and 5.11 of the International Conference on Harmonization Guideline for Good Clinical Practice.

1.9 HRPP Resources and Oversight
The State College of Optometry, through the office of the Associate Dean for Graduate Studies and Research, ensures that the HRPP has sufficient resources sufficient to protect the rights and welfare of research participants for the research activities that the College conducts or oversees. The HRCC is responsible for maintaining oversight of research involving human subjects and enforcing compliance.

1.10 HRPP Policies on Transnational Research and Cultural Context of Human Subjects
The College adheres to the Food and Drug Administration (FDA) Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance. Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting research that involves the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well being of subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical research data are credible. The objective of the GCP guidelines is to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. These guidelines were developed with consideration of the
current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries, and the World Health Organization (WHO).

For investigator-initiated or sponsor/investigator collaborative research, both GCVR and CVRC staff will provide assistance to research investigators and/or sponsors to assess the need for changes to traditional recruitment and assessment protocols depending on the cultural context of the target population.

For sponsor-initiated trials, the GCVR and CVRC staff will provide assistance to principal investigators and sponsor/clinical research organizations to determine whether standard protocol structure and procedures are amenable to the cultural context of the population to be enrolled or require modification. Insofar as it is possible, the GCVR and CVRC staff will work with study personnel to implement culturally relevant recruitment and enrollment strategies.

The GCVR and CVRC staff will work with principal investigators to assess cultural context for all studies and help them plan for all aspects of participant and community interaction when appropriate, including dissemination of research findings. This includes meeting with relevant community leaders in order to ensure that the institution is fully aware of the cultural context for studies.

1.11 Informed Consent of Research Participants

Informed consent is an informed and voluntary decision by a potential subject about whether to participate in a research study based on full disclosure of the study procedures, potential risks, and benefits. Informed consent in can be viewed as a process involving an interaction between the person consenting and the person obtaining consent.

The informed consent obtained from all human subjects participating in research at or affiliated with the College strictly adheres to federal regulations as per FDA CFR Title 21 and HHS CFR Title 45. Discussions with potential human research subjects and the informed consent form include the following elements.

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

A key requirement in the informed consent process is that conversational and written language used to explain research to potential participants and obtain signed consent are in layman’s terms and in the speaking language of the participant. The process in obtaining informed consent from potential research subject participants includes the following steps:

• Potential participants are identified and the key elements of the research study are explained in oral or written form by qualified College personnel.
• Participants interested in participating in the study are given a more detailed explanation of key elements of the consent process including a detailed explanation of the consent form and all questions are answered.
• The participant is given a copy of the consent form for review and signature.
• Participants are offered a chance to ask any questions of qualified College staff.
• Participant and a College representative sign the consent form (and an assent form if the age of the participant is a factor) and a signed copy is given to the participant.

1.12 Community Outreach to Enhance Understanding of Human Research
All College faculty, staff, and students should take every opportunity to talk to patients and laymen in the community about the benefits of research carried out at the College. A “Participant Bill of Rights” is on display on all clinic floors and research exam rooms to reiterate the rights and benefits of research subject participants.

The Clinical Research Manager of the CVRC conducts outreach sessions within the local community, including PTAs and schools, to inform people about the importance of the research conducted at the College, the importance of human participants in the research, and the rights and benefits of being a research participant.
Educational material about the ongoing research at the College and the rights and benefits of being a research subject is disseminated in educational material offered on the school website and a patient newsletter. An important responsibility of the GCVR and CVRC is to assess the efficacy of the research information provided by the College to the community, including prospective research participants so as to continuously improve access to and understanding about human subject research.

1.13 HRPP Oversight and Compliance

The Human Research Compliance Committee (HRCC) and the IRB have the authority to inspect records, and to observe (or have a third party observe) the consent process and any approved research activity. The HRCC 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 randomly selected subject files for review by the HRCC. Depending on the responses provided, the HRCC will decide whether corrective actions are called for, ranging from acceptance of current practice to the need for on-site inspection. Improvements to oversight, including audits, will be made as necessary to ensure compliance of research activities to IRB-approved protocols and the College HRPP. Likewise, the HRCC can suggest changes to the College HRPP to increase its overall quality, efficiency, and effectiveness.

1.14 Feedback from Researchers and Research Staff Concerning HRPP Policies and Procedures

Researchers and research staff who have concerns or suggestions regarding the College HRPP are encouraged to convey them to the Director of the HRCC, Director of the IRB, Associate Dean, or other responsible parties (e.g., College Dean, departmental Chairs) regarding the issue, when appropriate. The HRCC, reporting to the Associate Dean, will research the issue, and when deemed necessary, convene the parties involved to form a response to the investigator or make necessary procedural or policy modifications, as warranted.

1.15 Violations of HRPP Policies and Procedures

1.15.1 Complaints

As part of its commitment to protecting the rights and welfare of human subjects in research conducted at the College, all complaints and allegations of non-compliance will be reviewed by the
Human Research Compliance Committee (HRCC) and it will take all necessary actions to ensure the ethical conduct of research. The HRCC will promptly investigate all complaints, concerns, and appeals received from staff, investigators, research participants, and others. This includes issues arising from internal audits. All complaints, regardless of point of origin, will be recorded and forwarded to the HRCC Chair. Upon receipt of the complaint, the HRCC Chair will make a preliminary assessment and assign it as an issue of non-compliance or an unanticipated event based on the criteria presented below.

1.15.2 Non-Compliance

All members of the College community involved in human subject research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional and IRB policies governing the conduct of research involving human subjects.

- **Non-compliance** is defined as the failure to comply with any of the regulations and policies described in this document and/or failure to follow an IRB-approved protocol for a research project. Non-compliance may be minor or sporadic or it may be serious or continuing.

- **Serious non-compliance** is defined as that which, in the judgment of either the HRCC Chair or the convened HRCC, increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research projects being conducted without prior IRB approval or participation of subjects in research activities without their prior consent (in studies where consent was not specifically waived by the IRB) are examples of serious non-compliance.

- **Continuing non-compliance** is defined as a pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

Violations of HRPP policies and procedures may be revealed during HRCC audits or may be reported by anyone to the Chair of the HRCC, Chair of the IRB, Associate Dean, or other school officials. Principal investigators and their research staff are required to report instances of possible non-compliance, which should be brought to the attention of the HRCC Chair, IRB Chair or their staff. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and cooperating with the institutional review of the allegation. If an individual, whether investigator, study staff or other, is uncertain whether there is cause to report noncompliance, he or she should contact the HRCC Chair, IRB Chair, or Associate Dean directly to discuss the situation informally.

Reports of non-compliance should be submitted to the HRCC Chair, IRB Chair, or Associate Dean...
within 10 working days of its discovery. The report should include a complete description of the non-compliance and the personnel involved. Complainants may choose to remain anonymous. The HRCC is responsible for investigating all allegations of non-compliance. The HRCC Chair will acknowledge receipt of the allegation to the Associate Dean, IRB Chair, complainant, and affected PI within 3 business days and will assign the HRCC to commence an investigation. All reports/allegations regarding human subject research activities made to the HRCC regarding human will be held confidential, to the extent allowed by law.

1.15.3 Review of Non-Compliance Allegation

The HRCC Chair, in consultation with the IRB Chair and Associate Dean if necessary, will make an initial review of the allegation. The HRCC Chair will determine if the allegation of non-compliance is serious enough to warrant immediate suspension of the research project, pending a complete review of the convened HRCC, to ensure protection of the rights and welfare of participants.

After this initial review, the convened HRCC will review the allegation. During the review process, the HRCC will examine all relevant documents, including the IRB approval letter, the approved IRB application and protocol, approved consent document, grant application, subject records, brochures, and questionnaires. It is the principal investigator’s responsibility to make all pertinent documents available to the HRCC. The HRCC may determine that additional expertise or assistance is required to make these determinations and may form an ad hoc committee to assist with the review and fact gathering process. The ad hoc committee will generate a report and present it to the convened HRCC. The minutes of all meetings will be generated to help support the findings and determinations of the review.

Based on this review, the HRCC will make a final determination as to the non-compliance allegation. When the HRCC determines that non-compliance did not occur because the incident was within the limits of an approved protocol for the research involved, the determination will be reported to the Associate Dean, IRB Chair, principal investigator and, if applicable, the reporting party. The determination letter will be copied to any other parties that had been notified at the outset. No further actions are necessary.

If the HRCC determines that non-compliance allegations are true, the non-compliance will be categorized as non-serious, serious, or continuing in order to determine what actions must be taken. The investigator is informed of the HRCC determination and the basis for the determination in writing and is given a chance to respond.
1.15.3.1 Final Review and Action

The HRCC will submit a report of the results of their inquiry to the IRB Chair. The report will then be reviewed at a convened IRB meeting. If the results of the inquiry substantiate the finding of serious or continuing non-compliance, the IRB’s possible actions may include, but are not limited to:

- Request a correction action plan from the investigator.
- Verification that participant selection is appropriate and observation of the actual informed consent.
- An increase in data and safety monitoring of the research activity.
- Request a directed audit of targeted areas of concern.
- Request a status report after each participant receives intervention.
- Modify the continuing review cycle.
- Request additional Investigator and staff education.
- Notify current subjects, if the information about the non-compliance might affect their willingness to continue participation.
- Modification of the protocol.
- Modification of the information disclosed during the consent process.
- Requiring current participants to re-consent to participation.
- Suspend the study (see below).
- Terminate the study (see below).

In cases where the HRCC determines that the event of non-compliance also meets the definition of unanticipated problem involving risks to subjects or others, the policy and procedure for review of such events will also be followed as detailed below. If the IRB determines that the non-compliance was serious or continuing, the results of the final review will be reported as described below in Reporting.

1.15.3.2 Suspension or Termination

The College IRB has the authority to suspend, terminate, or place restrictions on any study in which the investigator has not met the policies or procedural requirements of the College HRPP and/or in the event where information is disclosed to the HRCC and/or IRB that indicates that the rights and/or welfare of human subjects are at risk. Suspension of IRB approval is a directive of the convened IRB or IRB Chair either to temporarily or permanently stop some or all previously approved research activities. Suspended protocols remain open and require continuing review. Termination of IRB approval is a directive of the convened IRB to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.
The IRB Chair may suspend research to ensure protection of the rights and welfare of participants. Suspension directives made by the IRB Chair must be reported to a meeting of the convened IRB. In contrast, approved research may only be terminated by the convened IRB. Terminations of protocols previously approved under expedited review must still be made by the convened IRB.

The IRB Chair will notify the principal investigator, HRCC Chair, and Associate Dean in writing of such suspensions or terminations and will include a statement of the reasons for these actions. The terms and conditions of the suspension must be explicit. The investigator will be provided with an opportunity to respond in writing.

When study approval is suspended or terminated by the IRB Chair or convened IRB, in addition to stopping all research activities, any currently participating subjects will be notified that the study has been suspended or terminated. The IRB Chair or convened IRB will consider whether procedures for withdrawal of enrolled subjects are necessary to protect their rights and welfare. These procedures can include:

- Transferring participants to another investigator.
- Making arrangements for care or follow-up outside the research.
- Allowing continuation of some research activities under the supervision of an independent monitor.
- Requiring or permitting follow-up of participants for safety reasons.

If follow-up of subjects for safety reasons is permitted/required by the IRB Chair or convened IRB, the subjects will be so informed and that any adverse events/outcomes will be reported to the sponsor.

In accordance with the Federal Wide Assurance, the following violations will be reported by the HRCC Chair or IRB Chair to the Associate Dean, Vice President for Academic Affairs, President of the College, OHRP, and affected sponsor(s) where applicable:

- Unanticipated problems involving risks to subjects or others.
- Serious or continuing noncompliance with 45CFR46 or the determinations of the IRB.
- Violations resulting in suspension or termination of IRB approval.

If the HRCC or IRB determines that the violation involves possible scholarly or scientific misconduct, the Associate Dean will take appropriate action in accordance with established College assurances, policies, and procedures.
1.15.3.2 Investigator Hold
A principal investigator may request an administrative hold on a protocol to temporarily or permanently stop some or all approved research activities. Administrative holds are not suspensions or terminations.

Investigators must notify the IRB in writing that:

- They are voluntarily placing a study on hold.
- A description of the research activities that will be stopped.
- Proposed actions to be taken to protect current participants.
- Actions that will be taken prior to IRB approval of proposed changes in order to eliminate apparent immediate harm.

Upon receipt of written notification from the principal investigator, the IRB Chair will place the research on the agenda for review. The IRB Chair, in consultation with the IRB members, will determine whether any additional procedures need to be followed to protect the rights and welfare of current participants. The IRB Chair, in consultation with the IRB members, will determine how and when currently enrolled participants will be notified of the administrative hold.

1.15.3.3 Protection of Currently Enrolled Participants
Before an administrative hold, termination, or suspension is put into effect the convened IRB will consider whether any additional procedures need to be followed to protect the rights and welfare of current participants. Such procedures may include:

- Transferring participants to another investigator.
- Making arrangements for clinical care outside the research.
- Allowing continuation of some research activities under the supervision of an independent monitor.
- Requiring or permitting follow-up of participants for safety reasons.
- Requiring adverse events or outcomes to be reported to the sponsor.
- Notification of current participants.
- Notification of former participants.

1.15.3.4 Reporting
Serious or continuing non-compliance with HRPP regulations or the requirements or determinations of the IRB will be reported to the appropriate regulatory agencies and institutional officials. Federal regulations require prompt reporting to appropriate institutional officials and the department or agency head of:
• Any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB.
• Any suspension or termination of IRB approval.

The IRB will initiate these procedures subsequent to any of the following actions:

• A determination that an event may be considered an unanticipated problem involving risks to participants or others.
• A determination that an instance of non-compliance was serious or continuing.
• A suspension or termination of previously approved research.

The IRB Chair or designee will prepare a written report containing the following information:

• The nature of the event such as unanticipated problem involving risks to participants or others see Section 1.15.4 below), serious or continuing non-compliance, or suspension or termination of approval of research.
• Name of the institution conducting the research.
• Title of the research project and/or grant proposal in which the problem occurred.
• Name of the principal investigator on the protocol.
• Number of the research project assigned by the IRB and the number of any applicable federal awards (grant, contract, or cooperative agreement).
• A detailed description of the problem including the findings of the organization and the reasons for the IRB’s decision.
• Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).
• When an investigation has been completed or a corrective action plan has been implemented.

The IRB Chair and the IO will review the report letter and modify it as necessary. The IO will then sign the report and return it to the IRB Chair who will send a copy of the report to the following people, committees, and agencies:

• Members of the IRB by including the report letter in the next agenda packet as an information item.
• The Institutional Official.
• The OHRP, if the study is subject to DHHS regulations or subject to a DHHS federal wide assurance.
• The FDA if the study is subject to FDA regulations.
If the study is conducted or funded by any Federal Agency other than DHHS that is subject to “The Common Rule”, the report is sent to OHRP or the head of the agency as required by the agency.

- The principal investigator.
- The sponsor of the study.
- Any contract research organization affiliated with the study.
- The chairman or supervisor of the principal investigator.
- Others as deemed appropriate by the IO.

The IRB Chair will ensure that all steps of this policy are completed within 10 days of the initiating action. For more serious actions, the IRB Chair will expedite reporting.

### 1.15.4 Unanticipated Problems

Federal regulations require organizations to have written policies and procedures to ensure the prompt reporting of unanticipated problems involving risks to subjects or others to the IRB, appropriate institutional officials, and regulatory agencies and departments.

An unanticipated problem is defined as any event, any incident, experience, outcome, or new information that was unforeseen and indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. An event is unanticipated when its specificity and severity are not accurately reflected in the informed consent document, protocol and/or the research brochure. The incident, experience or outcome is not expected in terms of nature, severity, or frequency given the research procedures that are described in the protocol-related documents such as the IRB-approved research application.

Not all unanticipated problems involve direct harm to subjects. Events can occur which are unexpected and result in new circumstances that increased the risk of harm to subjects without directly harming them. In addition, the event may have presented unanticipated risks to others (e.g., the sexual partners of the subjects, individuals the subject may come in contact with, family members, research personnel, etc.) in addition to the subjects. In each case, while the event may not have caused any detectable harm or adverse effect to subjects or others, they nevertheless represent unanticipated problems and should be promptly reported.

Events that cause direct harm to subjects are referred to as “adverse events”. An adverse event is any physical, psychological or social harm to subjects during the course of research. An adverse event can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article. Although
adverse events occur most commonly in the context of biomedical research, adverse events can also occur in the context of social and behavioral research. Only unanticipated adverse events that are related to the research need to be reported. An event is related to the research procedures if, in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely that not that the event affects the rights and welfare of current participants.

1.15.4.1 Reporting
Principal investigators must report to the IRB as soon as possible, but in all cases within 5 working days of any:

- Adverse events which in the opinion of the principal investigator are both unexpected and related.
- An unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk.
- Information that indicates a change to the risks or potential benefits of the research. For example:
  - An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
  - A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.
- A breach of confidentiality, including the loss of digital storage devices.
- A change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
- A complaint from a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
- A protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm.
- Any event that requires prompt reporting to the sponsor.
- A sponsor-imposed suspension for risk.

The principal investigator should first contact the HRSCC or IRB Chair Office by email or telephone to determine if the reporting is necessary. If so, principal investigators should report the event above event to the HRSCC and IRB Chairs using the Unanticipated Event Report Form.
1.15.4.2 IRB Review

Upon receipt of an *Unanticipated Event Report* from a principal investigator by the HRSCC or IRB Chair, it will be reviewed and, based on the report, they may suspend research to ensure protection of the rights and welfare of participants. Suspension directives made by the IRB or HRSCC Chair will be reported to the Associate Dean and members of the IRB and HRSCC.

The report will be forwarded to members of the HRSCC, which will investigate and discuss the event at a convened hearing. The HRSCC may require submission of more detailed contextual information from the PI concerning the unanticipated event. The HRSCC will determine whether the there was in fact an unanticipated event, whether participants were harmed, and whether participants are at increased risk of harm. The HRSCC will prepare a report and submit it to the IRB Chair.

The HRSCC report will be reviewed at a convened meeting of appropriate action will be taken depending on the nature of the risk involved, including modification of the protocol or the consent form, if applicable. In addition to the HRSCC report, the IRB will review the currently approved protocol, the approved consent document, the investigator’s brochure, and any previous reports of unanticipated problems. Based on the review, the IRB will make recommendations based on the following considerations:

- Whether the reported event is an unanticipated problem involving risks to participants or others according to the definition in this policy.
- What action in response to the report is appropriate.
- Whether suspension or termination of approval is warranted.
- Whether further reporting to Institutional and/or federal officials is required.

If the IRB concurs that the event to not represent an unanticipated problem the results of the review are recorded in the protocol record, the IRB minutes and communicated to the investigator. The IRB may recommend any of the following actions:

- Nothing further.
- Requiring modifications to the protocol.
- Revising the continuing review timetable.
- Modifying the consent process.
- Modifying the consent document.
- Providing additional information to current participants (e.g. whenever the information may relate to the participant’s willingness to continue participation).
- Providing additional information to past participants.
- Requiring additional training of the investigator and/or study staff.
- Other actions appropriate for the local context.
In the case of an unanticipated event, the IRB will consider the following actions:

- Modification of the protocol.
- Modification of the information disclosed during the consent process.
- Providing additional information to current participants (This must be done whenever the information may relate to the participant’s willingness to continue participation).
- Providing additional information to past participants.
- Requiring current participants to re-consent to participation.
- Alteration of the frequency of continuing review.
- Observation of the research or the consent process.
- Requiring additional training of the investigator and/or study staff.
- Notification of investigators at other sites.
- Termination or suspension of the research.
- Obtaining additional information.
- Referral to other organizational entities (e.g., legal counsel, risk management, institutional official).

The results of the IRB review are recorded in the IRB minutes, protocol record, communicated to the investigator and referred to the IRB Office to be handled according to the reporting procedures.

### 1.16 Financial Conflicts of Interest (FCOI)

A FCOI can result from a significant financial interest that is related to and that could directly and significantly affect the design, conduct, or reporting of externally and applicable internally supported activities. All personnel involved in a research project must provide a signed Conflict of Interest form together with the Research Authorization Form to the Associate Dean and Office of Sponsored Research. When the activity involves human subjects, per OHRP and/or FDA as applicable, the Sponsored Program Officer will review the Conflict of Interest form and make an independent decision regarding presence of FCOI. The Conflict of Interest form must be submitted annually.

The responsibilities and obligations of investigators and staff to the College must be clearly separated from personal financial interests or other obligations. Prudent stewardship of public funds requires protecting College research, education and public service from being compromised by the private interests or obligations of any investigator or staff member. SUNY and Research Foundation (RF) investigators and staff may not have any interest in or engage in any outside activity, which results in unmanaged Financial Conflict of Interest. To this end, SUNY and RF investigators and staff must disclose their interests and outside activities, and those of a related party, which may affect their independent and objective performance of their research project(s). FCOI shall be subject to management plans and compliance with such management plans shall be
The State College of Optometry’s Financial Conflict of Interest Policy is available to all College employees on the College website as well as in hardcopy handbook form. It includes definitions of conflicting financial interest and outlines procedures for recusal from committees or meetings where a potential conflict may arise. To avoid potential FCOI, administrators, investigators and research staff within the College must adhere to the following policies.

- Administrators, investigators and research staff shall not accept other employment that will impair their independence of judgment in the exercise of their duties and responsibilities.
- Administrators, investigators and research staff shall not accept employment or engage in any business or professional activity that will require them to disclose information confidential to the College that they have gained by reason of their position or authority.
- Administrators, investigators and research staff shall not disclose information confidential to the College acquired by them in the course of their duties except as required by law nor shall they use such information to further their personal interests, unless such information has previously been made public.
- Administrators, investigators and research staff shall not use or attempt to use their position to secure undue privileges or exemptions for themselves or others.
- Administrators, investigators and research staff shall not engage in any transaction as a representative or agent of the College with any business entity in which they, their spouse or any dependent, or any business partners have a direct or indirect financial interest that might conflict with the proper discharge of their duties or responsibilities.
- Administrators, investigators and research staff shall not by their conduct give reasonable basis for the impression that any person can improperly influence them or unduly enjoy their favor in performance of their duties, or that they are affected by the kinship, rank, position or influence of any party or person.
- Administrators, investigators and research staff shall abstain from holding personal investments in enterprises that they have reason to believe may be directly involved in decisions to be made by them or that will otherwise create conflict between their duties in the best interests of the College and their private interests.
1.17 Use of Investigational or Unlicensed Test Articles
All studies involving investigational or unlicensed test articles must be assessed for regulatory approval or exemption. This includes PI/sponsor providing Investigational Device (IDE) or Investigational New Drug (IND) numbers when appropriate. If the investigational or unlicensed test article does not require an IND or IDE, written justification for exemption must be submitted to the HRPP.

1.18 Handling of Investigational or Unlicensed Test Articles
The College follows all protocol requirements for proper storage and usage of investigational or unlicensed test articles. Trained certification is required for all personnel who deal with shipping hazardous materials. The College follows the Mayo Clinic’s Dangerous Goods Training to perform and verify training of SUNY employees. This training program can be found online at: http://www.mayomedicallaboratories.com/education/online/dangerousgoods/index.html

1.18.1 Emergency Use of Investigational or Unlicensed Test Articles
The College follows Food and Drug Administration (FDA) regulations when conducting research involving a test article in a clinical investigation involving human subjects as defined by the FDA regulations. Specifically, State College of Optometry applies the FDA regulations at 21 CFR 50 and 21 CFR 56, as well as, where appropriate, 45 CFR 46.

The PI must indicate on the Administrative Research Approval form whether the research involves investigational drugs or devices. If so, the PI must indicate if there is an Investigational New Drug or Device Exemption for the research and provide documented assurance from the sponsor that the investigational or unlicensed test articles conform to federal regulations.

1.19 Application of College HRPP to Public, Industry, and Private Sponsors
The State College of Optometry works with the public, industry and private Sponsors to apply the requirements of the Human Research Protection Program (HRPP) to all participants. To accomplish this, the College has written agreements with Sponsors addressing issue of subject recruitment and participation and the medical care for research participants who may suffer with a research-related injury.

Prior to the start of any clinical research involving human research participants, arrangements for medical care for research-related injuries are defined including, who will provide such care and who will be responsible for paying for the care. Information specifying financial and medical responsibility for these injuries is clearly presented to the research participant in the informed
consent and includes instructions concerning where medical treatment should be sought if injury occurs and whom to contact in the event of a research-related injury.

In studies where a sponsor bears responsibility for monitoring of the research, the College will have a written plan with the sponsor so that the sponsor promptly reports to the College findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB’s approval to continue the study. When participant safety or medical care could be directly affected by study results, State College of Optometry addresses in the written agreement with the sponsor how results will be communicated to study participants.

In adherence to federal regulations, research plans submitted to the IRB provide adequate provisions for monitoring data collected in order to ensure the safety of subjects. Monitoring is commensurate with risks and with the size and complexity of the research trials.

For projects requiring a data safety and monitoring plan when the sponsor has the responsibility to conduct data safety and monitoring, the protocol must address provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the College and must specify the time frame for providing routine and urgent data and safety monitoring reports to the College. Clinical research agreements include compliance with sponsor obligations as articulated in the Research Approval Form.

When the IRB learns of events that could affect participant welfare after a study has closed (e.g., a drug studied at the College is withdrawn by the FDA), the IRB seeks information, deliberates, and considers whether (and how) to contact participants who might be affected. Even when the study is not yet closed, but participants have completed participation, the IRB informs former participants when information is learned that could affect their welfare.

In clinical sponsored research settings, there is frequent communication between various College personnel, including the IRB, and the sponsor about monitoring of the study and any issues that might affect the continuation of the study. Such discussions commonly occur between the Principal Investigator or his/her study coordinator and the sponsor. In addition, the sponsor's written plan for the dissemination of findings that could impact the safety or participation of research participants must be contained in the Research Approval Form, which is considered an integral part of the research agreement.
2. Institutional Review Board

2.1 Institutional Review Board Roster

A membership list of the College Institutional Review Board (IRB) is maintained by the Associate Dean and identifies members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list contains the following information about members:

- Name and earned degrees.
- Affiliated or non-affiliated status. Neither a non-affiliated member nor his/her immediate family members may be affiliated with the university.
- Status as scientist: physician-scientist, other scientist, non-scientist or social behavioral scientist. For purposes of this roster, IRB members with research experience are designated as scientists. Research experience includes training in research (e.g., doctoral degrees with a research-based thesis) both previous and/or current. Students being trained in research fields will be designated as scientists.
- Indications of experience, such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations.
- Representative capacities of each IRB member such as which IRB member is a prisoner representative or and which IRB members are knowledgeable about or experienced in working with children, pregnant women, cognitively impaired individuals, and other vulnerable populations locally involved in research.
- Role on the IRB (Chair, Co-Chair, etc.).
- Voting status (Any ex officio members are non-voting members).
- For alternate members, the primary member or class of members for whom the member could substitute.
- Relationship (e.g., employment) between the individual IRB member and the College.

Per federal guidelines, the College IRB will consist of:

- One or more unaffiliated members.
- One or more members who represent the general perspective of participant.
- One or more members who do not have scientific expertise.
- One or more members who have scientific or scholarly expertise and, when the IRB regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.

The GCVR office keeps the IRB membership list current. The Associate Dean for Graduate Studies and Research promptly reports changes in IRB membership to the Office for Human Research.
Members of the IRB are recommended by the Associate Dean for Graduate Studies to the Vice President for Academic Affairs and to the President of the College, as designated on State College of Optometry’s Federal Wide Assurance (FWA), following consideration of recommendations from applicable administrators, current IRB members, and/or members of the community (for non-affiliated positions). The President of the College makes all appointments to the IRB.

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 IRB 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 IRB members. No IRB member participates in the review of any study on which he/she 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 on occasions when the chair has a conflict of interest and for time-sensitive matters pertaining to human subject protections when the IRB Chair is unavailable.

Members are responsible for ensuring that the rights and welfare of research subjects are protected. Members vote to approve, require modifications in, disapprove, or defer research submitted to the IRB. Members are expected to attend IRB meetings on a regular basis, serve as primary reviewers for research within their areas of expertise, and serve as general reviewers of all research. Members may also be asked to participate in subcommittees, audits, and education, as long as there is no conflict of interest with their IRB responsibilities or their other personal or professional roles.

The IRB 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 IRB meetings to clarify issues with the members concerning their proposed research activity. Such guests do not take part in committee deliberations or voting.

2.1.1 Managing Conflicts of Interest of IRB Members
The College recognizes that officials who administer research programs, and individuals who are responsible for development activities (including raising funds), may represent competing business interests, or be in a position to influence programmatic and budgetary decisions and exert undue influence on the IRB or its individual members. To avoid such influence on IRB determinations, the
Associate Dean of Graduate Studies, the Dean of Academic Affairs, and other College officers will not serve as voting members of the IRB, unless there are compelling reasons to do so. Such reasons must be justified in writing, approved by the College President, and include specific measures to manage any conflict of interest or the possibility of undue influence.

The State College of Optometry Financial Conflict of Interest Policy describes principles and procedures designed to ensure that research involving human subjects at State College of Optometry is conducted without untoward influence resulting from either the University's financial investments or holdings or the personal financial interests or holdings of key institutional leaders, which can include the President, the Provost, the Vice Provost and Dean of Research, School Deans, Senior Associate Deans, Department Chairs, Division Chiefs, and Institute and Center Directors (see Section 1.17). This policy applies when protocols and reports are first received by members assigned to review, during discussion, and during final voting in convened meetings. This policy applies to all projects reviewed by the IRB, regardless of whether the project is exempt or considered during full, expedited, or continuing review. This policy also applies to reviews of non-compliance reports and unanticipated problems involving risks to participants or others.

All research proposals submitted by College faculty involving human subject research are initially reviewed by the Sponsored Research Officer or CVRC Manager. This review occurs when the proposal is submitted for funding to an extramural sponsor or in meeting their obligation to provide scientific evaluation when internal funds are used to support a human subjects research project. As part of this review, applicants and reviewers must identify any personal financial conflict of interest, regardless of value, that he or she has in the research sponsor or in an entity that owns or controls the investigational product that is the subject of the research.

IRB submission procedures take into account conflicts of interest when assigning new protocols to an IRB, such as when any IRB member is named in the research protocol or has a spousal relationship with any research personnel. IRB members who realize they have a conflicting interest when they are first assigned a protocol or report for review must notify the IRB Chair immediately so that the protocol can be reassigned.

IRB members review the draft Agenda List before a convened meeting with the issue of conflicts in mind. Any conflicting interest for protocols to be voted on must be reported to the IRB Chair before the meeting whenever possible. The IRB Chair begins each meeting with a reminder that proceedings are confidential followed by a reminder of the requirement that each member must disclose any conflicting interest and recuse him or herself from the discussion of and the vote on the project by leaving the room, except if the member is providing information at the IRB’s request. If an IRB member realizes at a meeting that he or she may have a conflicting interest in a given project, then that should be disclosed to the IRB Chair immediately orally and in writing.
2.2 Documentation of IRB Activities

2.2.1 IRB Meeting Procedures

The IRB meets on a regular basis throughout the year. The schedule for the IRB may vary due to holidays or lack of a quorum. The schedule for IRB meetings is available in the GCVR office and on IRBNet and is posted for the benefit of all investigators, research coordinators, and other research staff when submitting protocol materials. The deadlines for applications requiring full committee review at a convened meeting of IRB is approximately two and one-half weeks prior to the next meeting date. Additional full board review meetings are scheduled as needed.

A quorum consists of a simple majority (more than 50%) of the voting membership, including at least one member whose primary concern is in a non-scientific area. The non-scientific member, the unaffiliated member, and the member representing the general perspective of subjects, may be the same person or at times may be represented by two or three different members. If research involving an FDA-regulated article is involved, a licensed physician must be included in the quorum. The IRB Chair will confirm that an appropriate quorum is present before calling the meeting to order. The IRB Chair will be responsible to ensure that the meetings remain appropriately convened. The meeting minutes will document member attendance and the status of the quorum.

A quorum must be maintained for each vote to occur. Quorum is monitored throughout the meeting by the IRB Chair and is re-assessed each time a member leaves and enters the meeting room. Quorum will be lost if the only non-scientific member leaves the room, even if half of the members are still present. Quorum may be lost if the only unaffiliated member or only member representing the general perspective of subjects leaves the room. If a quorum is not maintained, the research must not be voted on and will be deferred. No official action or vote will be taken by the board if a quorum is lost during a meeting. Opinions of absent members that are transmitted by mail, telephone, facsimile, or e-mail may be considered by the attending IRB members, but may not be counted as votes or to satisfy the quorum for convened meetings.

2.2.2 The IRB Minutes

Present GCVR staff will keep the minutes of all IRB meetings. The minutes will include:

- Meeting attendees and invitees.
- Discussions and actions taken by the IRB including all deliberations for each action.
- Determinations made by the IRB and the protocol-specific findings that justify those determinations.
- Votes for each action recorded as numbers for, against, or abstaining.
- Other issues requiring convened IRB review.
2.2.2.1 Attendance at an IRB Convened Meeting

Attendance at an IRB convened meeting is recorded in the minutes by documenting:

- The IRB members (voting, non-voting, and *ex-officio*) who are in attendance. Non-voting members include *ex-officio* members or alternate members attending for informational purposes.
- The IRB members who are not in attendance.
- When an alternate member replaces a primary member in attendance and voting at the convened meeting.
- The continued presence of quorum for all votes, including a member whose primary concern is in a nonscientific area.
- Attendance of members and alternate members who participate through videoconference or teleconference, and documentation that those members received all pertinent material before the meeting and had the opportunity to actively and equally participate in all discussions.
- The IRB members who leave the meeting because of a conflicting interest.
- The IRB members who leave the meeting briefly, are not present during a vote, and are not counted as part of the quorum.
- The IRB members who arrive late or depart early from the meeting and their arrival or departure times.
- The GCVR staff present.
- Any others present (e.g., invited guests, investigators invited to address the IRB, and consultants).

2.2.2.2 Discussions, Determinations, and Actions Taken By the IRB

Discussions and actions taken by the IRB, including the deliberations that form the basis for each action, are documented in the minutes. These items should include:

- Discussion of protocol events – new, continuing review, modifications, reports of unanticipated problems and events and information requiring prompt review.
- Approval of research – including the approval period for research, at initial and continuing review, (and if appropriate to the degree of risk determination of an approval period of less than one year).
- Approval of research contingent on specific minor conditions, and the designee (staff or Panel member) appointed to sign off on the condition when met. If the condition is met after the minutes for that meeting are approved, the approval is documented in the minutes of the first IRB meeting that takes place after the contingency is met.
Determinations made by the IRB are recorded in the minutes with documentation of the protocol-specific findings justifying those determinations as appropriate. These findings can include:

- Significant risk and non-significant risk device determinations.
- Approval of waiver or alteration of informed consent.
- Waiver of informed consent documentation.
- Research involving adults with impaired decision-making.
- Waiver or alteration of HIPAA Authorization.

When research involves children or others of limited capacity, the following IRB decisions are documented:

- Whether procedures will recruit children appropriate and applicable to the research program.
- Whether the permission of one parent/guardian is sufficient or if permission from both parents/guardians is required.
- How assent is to be solicited or obtained, unless waived.
- Whether children who are wards of the state is approved.
- Appropriate involvement of pregnant women, fetuses, and neonates.
- Approval of research involving prisoners as participants as determined based on the level of risk.

2.2.2.3 Disposition of the IRB Minutes
The GCVR staff writes the minutes and makes them available for IRB review within three weeks of the meeting date. Minutes may not be altered by anyone once approved by the members at a subsequent IRB meeting. The minutes of convened IRB meetings are considered confidential and access to them is restricted and secured.

2.3 The IRB Review Process

2.3.1 Initial Review
The Sponsored Research Officer or CVRC Manager will perform a preliminary review of all protocol materials uploaded onto IRBNet for determination of completeness, accuracy, and required initial signatures. Only complete submissions will be placed on the IRB agenda for review. The investigator will be informed of missing materials and the necessary date of receipt for inclusion on that month’s agenda. In the case of a principal investigator who is submitting a protocol for the first time or an investigator who may not be well versed in the protocol submission procedures, individualized consultations can be arranged with the Sponsored Research Officer (SRO). In addition, the IRB will not perform a review of an application until it receives a completed Research
Authorization Form and Conflict of Interest form signed by the Associate Dean, Operations Manager, and, when appropriate, Director of the University Eye Center.

Applications that are deemed complete by the SRO are forwarded to the IRB Chair who determines the type of review: full committee, expedited, or exempt. This determination is based upon an assessment of the risk and therapeutic benefit associated with the study procedures. Risk can be considered minimal or more than minimal. Minimal risk is defined in 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 (45 CFR 46.102).

2.3.2 Expedited Review Procedure
Once the SRO receives an IRB proposal, it is forwarded to the IRB chair, who will determine whether a research application meets all criteria for expedited review (e.g., minimal risk, applicability to one of the categories referenced above). If so, the application materials are sent to one or more experienced reviewers, chosen from among the members of IRB. In reviewing the research in the expedited review category, the reviewers may exercise all of the authorities of IRB except that the reviewer(s) may not disapprove the research (disapproval may only be decided at a meeting of the full committee).

Under an expedited review procedure, the review may be carried out by one or more reviewers designated by the IRB Chair from among members of the IRB. Selected reviewers will be knowledgeable of the requirements to approve research under expedited review. IRB members with a conflict of interest in the research will not be selected.

When reviewing initial or continuing research under an expedited review procedure, the designated IRB member(s), will have access to all documentation as well as uploaded pre-screen comments from the SRO and IRB Chair and, in the case of a continuing review, all study history, which resides in IRBNet.

Investigators are notified by an IRBNet-generated e-mail when an action is taken on a study. 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, requires modifications/clarifications in order to secure approval, or is deferred for full committee review. If the modifications are administrative and/or minor, the IRB Chair may serve as final reviewer to determine if the investigator has sufficiently addressed the modifications. If the modifications are major, if the reviewer(s) request it, or if the IRB Chair deems it necessary, the modified submission will be sent back to the designated IRB member(s) for further review. If the reviewer determines that the research does not meet the criteria for expedited review, then the reviewer will indicate
that the research requires full review by IRB and the protocol will be placed on the next available agenda for an IRB meeting.

In the event that expedited review is carried out by more than one IRB member and the expedited reviewers disagree, the IRB Chair will address the disparity with the reviewers. If agreement cannot be reached, the IRB Chair may make a final determination. The IRB Chair or Associate Dean may request full review of expedited protocols.

Approvals are granted for one 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 Associate Dean as to the granting of administrative approval to carry out the IRB-approved study.

2.3.3 Exempt Review Category

Principal investigators may request an exemption from IRB review by submitting an Exempted Research Form to the SRO. Research activities may qualify for exemption status (i.e., exemption from committee member review) if 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.

- 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.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. In this case information obtained must be recorded in such a manner that the human subjects cannot be identified, directly or through identifiers linked to the subjects. Also, there should be no disclosure of the human subjects' response outside of the research that 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.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available.
- 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 public benefit or service programs; procedures for obtaining benefits
or services under those programs; possible changes in or alternatives to those programs or procedures listed in the points above; or possible changes in methods or levels of payment for benefits or services under those programs.

- Retrospective case studies that include one, two, or three human subjects. Note that studies that include analysis of more than three human subject records, even if the final data include less than four subjects, is considered systemic research and are not exempt.

If the investigator believes that his/her proposed research activity involves no risk, and falls into one of the exemption categories, s/he can request an exempt review. The investigator must provide to the SRO an Exempted Research Form and the written protocol and research plan, all recruitment materials (e.g., letter of invitation, flyers), consent forms when appropriate, all survey or questionnaires, letter of permission for non-College performance sites, any grant applications or contracts, and verification of current human research protection training for all members of the research team.

The IRB Chair or designee reviews all requests for exemptions and determines whether the request meets the criteria for exempt research. The Chair selects designees who are qualified to review this category of submission based upon their expertise of the protocol content and knowledge of the regulations pertaining to the research. Individuals involved in making the determination of an IRB exempt status of a proposed research project cannot be involved in the proposed research. Reviewers cannot have any apparent conflict of interest. Decisions regarding approval of exempt research are made by the IRB Chair or the designee determined by the Chair.

The SRO 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 requires modifications/clarifications in order to secure approval. Approval is granted for one year and the principal investigator is required to submit continuing review materials in sufficient time to avoid any lapse between approval periods. Even though a study may be determined to be exempted research, the principle investigator must submit a Research Authorization Form and COI forms for administrative approvals prior to initiating the research program.

### 2.3.4 Full IRB Committee Review

After it has been determined that the protocol submission is complete, the IRB Chair will assign protocols for review paying close attention to the scientific content of the protocol, the potential reviewer’s area of expertise, and ensuring, where applicable, that a scientific and non-scientific perspective is represented. Two reviewers will be assigned to each protocol and a reviewer may be assigned several protocols or other research items for review. Reviewers are assigned to all
protocols requiring initial review, continuing review, and modifications. When a protocol is presented outside of the knowledge base of any of the IRB members, an outside consultant will be sought. Protocols for which appropriate expertise cannot be obtained for a given meeting will be deferred to another meeting.

The primary and secondary reviewers are responsible for:

- Having a thorough knowledge of all details of the proposed research.
- Performing an in-depth review of the proposed research.
- Leading the discussion of the proposed research at the convened meeting, presenting both positive and negative aspects of the research, and leading the IRB through the regulatory criteria for approval.
- Making suggestions for changes to the proposed research, where applicable.
- Completing all applicable IRB reviewer forms.

If both the primary and secondary reviewer are absent from the meeting, consensus shall be taken to determine if the study in question must be tabled for a review at a future meeting, or if the present members have sufficient information and expertise then review will proceed. Additionally, an absent reviewer can submit his/her written comments for presentation at the convened meeting, provided there is another member present at the convened meeting who can serve as the primary reviewer. It should be noted that all IRB members receive and are expected to review all studies in addition to the primary and secondary reviewers.

2.3.5 Continuing Review

The IRB will conduct a continuing review of all non-exempt, ongoing research at intervals that are appropriate to the level of risk for each research protocol, but not less than once per year. Continuing review must occur as long as the research remains active for long-term, follow-up of participants, even when the research is permanently closed to enrollment of new. Continuing review of research must occur even when the remaining research activities are limited to the analysis of private identifiable information.

The following is required for a continuing review:

- The initial application including any approved changes.
- The current consent document.
- The completed and approved Research Authorization Form with updated information regarding the number of subjects screened, enrolled, and withdrawn since the last approval.
2.3.6 Review of Proposed Modification of Approved Research

When a proposed change in a research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects. In such a case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the subjects' continued welfare.

All documents provided by the investigator are accessible to all IRB members. At the meeting, the Primary Reviewer presents an overview of the modifications and leads IRB through the completion of the regulatory criteria for approval. IRB will determine whether the research with the proposed modifications continues to meet the regulatory criteria for approval.

When the IRB reviews modifications to previously approved research, it considers whether information about those modifications might relate to participants’ willingness to continue to take part in the research and if so, whether to provide that information to participants.

2.3.7 Use of Consultants

When necessary, the IRB Chair may solicit individuals from the College or the community with competence in special areas to assist in the review of issues or IRB proposals, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB. The need for an outside reviewer is determined in advance of the convened meeting by the IRB Chair by reviewing the scheduled IRB proposals. The IRB Chair will ensure that all relevant materials are provided to the outside reviewer prior to the convened meeting. In the event that additional scientific or scholarly expertise cannot be obtained for a research proposal, the IRB Chair will defer the proposal to the next IRB meeting to ensure that an appropriate review is carried out.

When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence and there is not at least one member who is knowledgeable or experienced in work with such participants at the meeting, the IRB will defer the research proposal until such expertise can be obtained through the membership or consultation.

Written statements of consultants will be kept in IRB records. Key information provided by consultants at meetings will be documented in the minutes. Written reviews provided by the outside reviewer will be filed with the protocol. The IRB Chair or inviting IRB member reviews the conflict of interest policy for IRB members with consultants. Consultants must provide a completed Conflict of Interest form to confirm to the IRB Chair that they do not have a conflict of interest prior to review. Individuals who have a conflict of interest or whose spouse or family members have a conflict of interest in the research will not be invited to provide consultation. The consultant's findings will be presented to the full board for consideration either in person or in writing. These
individuals do not count for IRB quorum purposes and cannot vote on any issue before the IRB.

Ad hoc or informal consultations requested by individual members (rather than the full board) must be approved first by the IRB Chair. These consultations must be made in a manner that protects the researcher's confidentiality and is in compliance with the College conflict of interest policy.

2.3.8 Managing Conflicts of Interest of Consultants
The definition of conflicting interest as defined in the State College of Optometry Financial Conflict of Interest Policy extends to any consultant who may be asked to review a protocol. The IRB member who contacts a consultant to inquire about review of a project is responsible for asking if the consultant has a conflicting interest in the project. All consultants must fill out a Conflict of Interest Form for inclusion in the minutes of the meeting.

If a consultant with a conflicting interest is the only appropriate resource for the IRB, (e.g., is the only scientist with sufficient technical understanding of the project) and if that consultant has been asked to provide information to the IRB, then the conflict of interest must be disclosed to the IRB members reviewing the protocol or present in the convened meeting where the information is presented. Such a consultant is excluded from discussion, except to provide information requested by the IRB, and must leave the meeting room during discussion and voting.

GCVR staff must not participate in the review of research protocols, and must not make exempt determinations for research protocols in which they have a conflict of interest. GCVR staff who realize they have a conflicting interest when they see a protocol or report for review must notify the IRB Chair immediately so that the protocol can be reassigned.

2.3.9 Review of Proposed Participant Recruitment Methods, Advertising Materials and Patient Payment Arrangements
The IRB will review proposed participant recruitment methods, advertising materials and pay payment arrangements. Furthermore, the IRB determines whether such arrangements are fair, accurate and appropriate.

Methods of recruitment must be detailed in the application. The IRB evaluates this information in determining if the selection and recruitment of participants is equitable and if the study imposes fair and equitable burdens and benefits - such that one group of persons does not disproportionately receive the benefits compared to another group assuming the risks.

IRB members review this information and confirm that the recruitment and selection strategies are fair, equitable, and not misleading. If recruitment strategies fail to meet these requirements, the
protocol will not be approved as written and the principal investigator will be asked to modify the recruitment plan accordingly, as a condition of approval.

Investigators are required to provide details on all methods of recruitment proposed on a project, including how participants will be identified for recruitment. Guidance on recruitment is available from CVRC staff. Some common recruitment methods include recruiting from one’s own patients, seeking referrals from colleagues (via word of mouth or referral letters sent to colleagues) and advertisements.

2.3.10 Data and Safety Monitoring Plan
The IRB will review the data safety monitoring plan (DSMP) as detailed in the Research Authorization Form. The IRB also determines that the DMSP provides adequate protection for participants. A DSMP is established to assure that each research study has a system for appropriate oversight and monitoring of the conduct of the study to ensure the safety of participants and the validity and integrity of the data. The plan is developed by the investigator, included in the protocol, and submitted to the IRB for review and approval before the study begins. An appropriate plan must be commensurate with the risks, size, and complexity of the study.
To approve research, the IRB must determine that, where appropriate, the research plan makes adequate provisions for monitoring the data to ensure the safety of research participants. The IRB primary reviewer reviews the proposed DSMP and the administration and composition of the monitoring entity, when applicable. If additional expertise is needed, the IRB will seek input from persons with appropriate knowledge.

In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research. It shall evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

The IRB has policies and procedures to protect the confidentiality of research information, including:

- All paper IRB records are kept secure in locked filing cabinets or locked storage rooms in the GCVR office, which is closed and locked when unattended.
- IRBNet, the College’s electronic IRB web-based program, is hosted at an out-of-state, enterprise class, data facility. Facilities are secure, data are mirrored, and IRBNet's data are backed up nightly to off-site fire-rated facilities. Authorized users have restricted access to the facility. Security precautions are state of the art. Security standards associated with user ids and passwords are in accordance with generally accepted commercial and federal security. Certified SSL (128 bit Secured Socket Layer technology) encryption is standard for all web-based transmissions. Strict permission
rules ensure that only approved individuals have access to Optometry data.

- Access to IRB records, whether paper or electronic, is limited to the Associate Dean, IRB Chair, IRB members, GCVR staff, authorized institutional officials, and officials of Federal and state regulatory agencies (OHRP, FDA). Department of Defense-sponsored research may require submitting records to Department of Defense for archiving. Research investigators are provided reasonable access to files related to their research. Appropriate accreditation bodies are provided access and may recommend additional procedures for maintaining security of IRB records. All other access to IRB records is limited to those who have legitimate need for them, as determined by the Associate Dean.
- Records are accessible for inspection and copying by authorized representatives of Federal regulatory agencies during regular business hours.
- Paper records may not be removed from the GCVR Office. However, the GCVR staff will provide copies of requested records to authorized personnel.
- All other access to IRB study files, paper or electronic, is prohibited.

2.3.11 Record Retention

Records pertaining to all IRB approved studies must be retained by the principal investigator for at least three years from date of notification to the IRB that the study has been completed or ended prior to completion.

2.4 Protection of Privacy Issues of Human Subjects

Privacy refers to persons and their interest in controlling the access of others to themselves. To approve research, the IRB must determine that, where appropriate, there are adequate provisions to protect the privacy interests of potential or current participants, from the screening and recruitment through all phases of research. If the protocol does not include adequate provisions to protect the privacy interests of the participants, the IRB may not approve the protocol as written.

The principal investigator must describe in the application the provisions for protecting the privacy of participants during screening, data collection and other interactions. The IRB assesses the information during the review process and at convened meetings. As necessary, the IRB will ask for additional details during its review.

Provisions for protecting the privacy interests of participants or participants should ensure that conditions under which a procedure is performed or information is collected (e.g., physical locations, telephone contact, mail or email solicitations) afford protections against interactions with participants being witnessed, overheard or inadvertently intercepted or viewed. For example, a
potential or current participant may feel uncomfortable being seen entering a place that they feel might stigmatize them, such as a pregnancy counseling center; having physical measurements recorded in a non-private setting; discussing private medical information in a setting with other than a health care provider or in other than a private clinical setting; or answering sensitive questions by telephone while at home or work. It is therefore important to limit the information being collected to only the minimum amount of data necessary to accomplish the research purposes.

2.4.1 Research Participants Protection

The IRB will ensure that there are adequate provisions to protect the privacy of research subjects and to maintain the confidentiality of data. Privacy refers to persons and their interest in controlling the access of others to themselves. To approve research, the IRB must determine that, where appropriate, there are adequate provisions to protect the privacy interests of potential or current participants, from the screening and recruitment through all phases of research. If the protocol does not include adequate provisions to protect the privacy interests of the participants, the IRB may not approve the protocol as written.

The principal investigator must describe in the application the provisions for protecting the privacy of participants during screening, data collection and other interactions. The IRB assesses the information during the review process and at convened meetings.

2.4.2 Maintenance of Confidentiality of Identifiable Data

Confidentiality refers to maintenance of the researcher’s agreement with the participant about how the participant’s identifiable private information will be handled, managed, and disseminated. As a condition of protocol approval, the IRB determines that there are adequate provisions to protect confidentiality of information related to potential or current participants, throughout the research, including data analysis and retention. PIs are expected to design studies to maximize confidentiality to avoid unintentional and unauthorized release or other disclosures.

The principal investigator must describe the provisions to protect the confidentiality of data in the application to the IRB. The IRB assesses the information provided in the application during the review process and at convened meetings. The IRB may ask for additional details during its review, depending on the sensitivity of the information being used, maintained or disclosed. Generally, the greater the sensitivity of the information, the more stringent the security measures that are needed.

The IRB must be informed in writing for approval before any deviation from the data protection plan described in the application. This includes any dissemination of protected and confidential data.
2.4.3 De-Identification of Health Information

Under HIPAA’s Privacy Rule, there are two approaches to de-identify health information so that it is no longer protected health information (PHI). Protected health information under HIPAA is individually identifiable health information. Identifiable refers not only to data that is explicitly linked to a particular individual (that’s identified information). It also includes health information with data items which reasonably could be expected to allow individual identification. Potential identifiers include obvious ones like name and social security number, and also:

- All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and [t]he initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Voice and fax telephone numbers.
- Electronic mail addresses.
- Medical record numbers, health plan beneficiary numbers, or other health plan account numbers.
- Certificate/license numbers.
- Vehicle identifiers and serial numbers, including license plate numbers.
- Device identifiers and serial numbers.
- Internet Protocol (IP) address numbers and Universal Resource Locators (URLs).
- Biometric identifiers, including finger and voice prints.
- Full face photographic images and any comparable images.
- Any other unique identifying number, characteristic, or code.

Under HIPAA’s "safe harbor" standard, information is considered de-identified if all of the above have been removed, and there is no reasonable basis to believe that the remaining information could be used to identify a person. The covered entity may assign a code or other means of record identification to allow de-identified information to be re-identified, if the code is not derived from, or related to, the removed identifiers. (Only the covered entity will have the re-linking information.)

Alternatively, under the "statistical" standard, a covered entity may determine that health information is not individually identifiable (and thus protected) health information if a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, applying such principles and
methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and that person documents the methods and results of the analysis that justify such determination.

As an alternative to using fully de-identified information, HIPAA makes provisions for a limited data set from which direct identifiers (like name and address) have been removed, but not indirect ones (such as age). Limited data sets require a data use agreement with the party to which/whom it is provided.

2.5 Suspension or Termination of IRB-approved Research

Investigators who conduct IRB-approved activities are responsible for promptly reporting any unanticipated problems involving risks to subjects or others. In addition, investigators must report such problems to the Associate Dean, IRB Chair, and the SRO.

The IRB Chair has the authority to suspend, terminate, or place restrictions on any study in which the investigator has not met the policy or procedural requirements and/or in the event where information is disclosed to the Associate Dean, IRB Chair, or Human Subject Research Compliance Committee that indicates that the rights and/or welfare of human subjects are at risk.

Reports of violations of this policy will be investigated by the HRCC and a report supported to and brought before IRB at a convened meeting. The IRB will make a determination regarding the need for additional information/further investigation or need for immediate action. The Associate Dean, and the affected Chair and Dean will be copied on all correspondence between the IRB and the involved parties. Upon determination that a violation of this policy has occurred, possible sanctions considered by IRB can include 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.

In situations where subject safety is involved, and/or the violations are apparent, the IRB Chair, 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. If the IRB determines that the violation involves possible scholarly or scientific misconduct, the Associate Dean will be notified and appropriate action will be taken in accordance with established College assurances, policies, and procedures. All reports/allegations regarding human subject research activities made to the HRCC and/or IRB will be held confidential, to the extent allowed by law.

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

- Any unanticipated problems involving risks to subjects or others.
- Any serious or continuing noncompliance with 45CFR46 or the determinations of the IRB.
- Any suspension or termination of IRB approval.

2.6 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.

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.

Informed consent is a continuing process whereby the investigator and research participant have an on-going dialogue about all aspects of a research study that might inform a participant’s decision to take part in the study, and their decision to continue their involvement as a participant. Although consent is given it may be withdrawn at any point. The informed consent process should be regarded as continuing throughout the duration of the research. The purpose of the consent process is to assure knowledgeable decision-making and voluntary participation.

2.6.1 Required Procedures to be followed by the Person Obtaining Consent

The individual who signs the consent form as the ‘person obtaining consent’ is responsible for leading the potential subject through the consent process, including:

- All aspects of the study, as described in the consent form, are first discussed with the potential subject,
- The consent form is thoroughly reviewed with the potential subject and answers to the potential subject’s questions are provided,
- 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).
The potential subject is given ample opportunity to decide, without coercion or undue influence, whether or not to be 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.

2.6.2 Determination of a Potential Subject’s Capacity to Consent to Research

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

- That the activity is research, not standard treatment.
- Of the risks and benefits of a study.
- Of the alternatives that are available if he/she does not participate.
- That, if he/she chooses not to participate, this decision will be accepted without penalty and will not jeopardize 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 for the items listed directly above, but may not care, or may actually want to take risks. Such individuals should not be considered able to provide consent for themselves.

2.6.3 Determination of a Subject’s Diminished Capacity

Certain individuals, such as those with severe dementia, or severe mental retardation, will have a diminished capacity to provide consent. For other individuals, it will not always be easy to predict whether capacity will be diminished given the following:

- Many individuals with psychiatric illnesses have the capacity to provide consent.
- Medical illnesses (e.g., cerebral insult) may be accompanied by an impaired capacity to consent.
- 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.
- Individuals who are intoxicated with alcohol or with drugs may be unable to consent to research until the intoxication resolves.
In assessing capacity, it is important to note that it is neither a constant nor an absolute. For example:

- Stroke victims may not have the capacity to consent to research immediately after the onset of stroke, but may develop capacity as recovery progresses.
- 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.
- Patients with schizophrenia often experience acute psychotic episodes followed by periods of lucidity.
- 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.

The requisite level of capacity will necessarily vary from study to study and will depend on the complexity of the information being presented and the relative risks and benefits of the study. For example, deciding to participate in a blood drawing protocol is ‘easier’ than 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).

### 2.6.4 Studies which include Individuals with the Lack of Capacity to Consent

The IRB will 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 that 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.
2.6.5 Representatives that can Provide Consent for Incapable Subjects
Individuals who may consent on behalf of the patient include:

- Individuals granted legally documented authority to make decisions specifically regarding participation in research activities
- Family members in order of priority: spouse, adult child, parent, adult sibling.
- Individuals named in a health care proxy.

2.6.6 Criteria for a Waiver of Obtaining Informed Consent
There the requirement for obtaining consent can be waived if the research involves no more than minimal risk to the subjects, the waiver or alteration will not adversely affect the rights and welfare of the subjects, and the research could not practicably be carried out without the waiver or alteration.

2.6.7 Criteria for a Waiver from the Documentation of Informed Consent
Federal regulations allow for a waiver of the documentation of consent if one of the following conditions is met:

- The only record linking the subject and the research will 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.
- 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 two conditions above. Nonetheless, the IRB will still require submission of either a consent ‘script’ (i.e., to verbally consent a subject) or a consent letter that does not require the subject to sign. In the latter case, the document is written in letter format rather than requiring the subject’s signature to verify consent.

2.7 Use of an External IRB
Normally, the SUNY Optometry IRB will review all human subject research under the jurisdiction of College faculty. Under certain circumstances, a project investigator may request that IRB review be ceded to an external IRB.
To avoid duplicating reviews, the SUNY Optometry IRB may cede review to OHSP (Office for Human Subject Protection)-certified external IRBs in the following circumstances:

- A multi-center trials where a single external OHSP-certified IRB is identified and has oversight of the project.
- When the college faculty investigator acts solely as a funded recipient of an award and no research activities will be taking place at the College or UEC facilities.
- When the faculty provides a subcontract for human studies work that is performed at another institution that either has, or will have, approval from an OHSP-certified IRB.
- If the involvement of the college faculty investigator is limited to data or specimen analysis collected through another institution’s OHSP-certified IRB.

Reviews will not be ceded to an external IRB:

- When the primary work involving human subjects takes place solely at the College or the UEC under the jurisdiction of college faculty investigators and the secondary institution’s involvement is primarily financial.
- When the study involves a secondary institution or institution’s personnel, but is initiated by an investigator from the College. Such studies may include but are not limited to: research at external sites and in private practices, research during clinical rotation curriculum of students, surveys and questionnaires, and research conducted at international sites.
- When the proposal has been reviewed by the SUNY Optometry IRB and determined to require revisions or has been rejected.

Requests to cede review to an external IRB must be made in writing to the Associate Dean with a copy sent to the College IRB chair. The request must include justifications and a summary of the study. Decisions to cede review will be considered on a case-by-case basis. The Associate Dean will review the request and make the final decision based on the guidelines described above. Should there be a significant question as to whether the request qualifies to be ceded to an external review board, the Associate Dean will seek guidance from the IRB Chair and its members. The Associate Dean will communicate a final decision to the principal investigator within 7 business days of receiving the request in most cases. When a review is ceded, the Associate Dean will write to the external IRB ceding review authority and will develop a formal written agreement delineating the roles and responsibilities of each party.

### 2.7.1 Written Agreements with External IRBs

When a project review is ceded to an external IRB, a formal written agreement will be developed that clearly delineates the roles and responsibilities of each party. In addition, there will be a
working and communicative relationship between the two parties. The role of the external IRB will be documented to ensure that the review is conducted according to all applicable regulations and laws, including initial review, continuing review, and review of modification to previously approved research. The external IRB will make available relevant IRB minutes to the College upon request. The agreement will specify the contact person and provide contact information for the reviewing IRB.

Researchers must comply with the determinations and requirements of the external IRB. Prior to the external IRB review the PI must provide the IRB with any local context issues relevant to the research protocol. Researchers and research staff agree to disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result.

The College retains responsibility for ensuring compliance with the IRB’s requirements at the research site. Research may be further reviewed and approved or disapproved by officials of the relying organization, but they may not approve the research if it has not been approved by the reviewing IRB. The College and the researchers acknowledge and agree to cooperate in the IRB’s responsibility for initial and continuing review, record keeping, and reporting. All information requested by the IRB will be provided in a timely manner. The College and researchers acknowledge that they are primarily responsible for safeguarding the rights and welfare of each research participant, and that the participant’s rights and welfare must take precedence over the goals and requirements of the research. The written agreement does not preclude the organization or researchers from taking part in research not covered by the agreement.

The agreement will stipulate whether the relying organization or reviewing IRB performs these responsibilities:

- Reporting to organizational officials, regulatory agencies, and sponsors of serious or continuing non-compliance, unanticipated problems involving risks to participants or others, suspensions or terminations of IRB approval.
- Education and continuing education of researchers and research staff. The educational requirements followed should be specified in the agreement.
- Obtaining disclosure and management of financial conflict of interest, although if the relying organization maintains responsibility for this issue, any disclosure or management plan will be proved to the IRB in timely manner prior to the decision by the IRB.
- Management of organizational conflict of interest related to the research.

**2.8 Multiple Site Research**

When the College serves as the coordinating institution of a multi-site research program, the
principal investigator must describe the plans for communicating information relevant to the protection of participants among the participating sites and institutions as part of the application, including communications of adverse outcomes, unanticipated problems, protocol modifications, and interim results. The IRB is responsible for the review of all College research involving human research participants, whether the research is conducted at the College, a College affiliate institution or another site outside the College.

In the application the investigator must indicate whether the College will serve as the coordinating institution. The principal investigator must list all other sites involved with the proposed research, the contact person at each site and contact information. In addition, the investigator must indicate if each participating site has an IRB and if that IRB has reviewed and approved the research. The College IRB will keep this information on file for all internal and external reviews.

For a prospective clinical trial, the consent forms used at all sites must indicate that data or samples are being sent to the SUNY College of Optometry. Data or tissue samples, even though they are anonymous, may not be received from an outside institution whose consent form prohibits data or tissue from going outside the institution.

There must be documentation of regular communication (e.g., teleconferences) with the participating sites to update and inform all participating sites about progress of the study. The principal investigator is responsible for receiving data and reports from the outside sites in a timely manner and distributing them to the College IRB as required. The College IRB will give the same considerations to such reports in multi-site research as they do to internal reports.
3. Investigator Responsibilities

3.1 Definition of Research

As defined by the Department of Health and Human Services, research is the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

All research at the College must adhere to all federal, state, and local laws and regulations as well as policies and procedures detailed in the HRPP. All human subject research must have approvals from both the College (or external) IRB as well as the administration (via an approved Research Authorization Form) prior to its initiation. It is the principal investigator’s responsibility to determine whether a study can be defined as research and thus needs IRB approval and, if not, the investigator must obtain an exemption from the IRB. All studies, whether they need IRB approval or are exempt from IRB review, must be approved by the College administration (via an approved Research Authorization Form) before they are initiated.

3.1.1 Prospective vs. Retrospective Studies

Prospective studies ask a question and look forward. The studies are designed before any information is collected. Study subjects are identified and followed forward to see if the outcome of interest happens over time. This outcome is assessed relative to the intervention factor. In prospective studies the investigators conceive and design the study, recruit subjects, and collect baseline exposure data on all subjects, before any of the subjects have developed any of the outcomes of interest. The subjects are then followed into the future in order to record the development of any of the outcomes of interest. The follow up can be conducted by mail questionnaires, by phone interviews, via the Internet, or in person with interviews, physical examinations, and laboratory or imaging tests. Combinations of these methods can also be used. Randomized controlled trials, considered the gold standard of study design, are prospective studies. They can provide evidence of cause-and-effect relationships and support changes in clinical practice or workplace interventions. In a randomized controlled trial, subjects are randomly assigned to receive the intervention or control treatment, and outcomes are evaluated after the intervention period. The control group is the group that receives standard care, no intervention or a placebo.

Retrospective studies pose a question and look back. They use information that has usually been collected for reasons other than research, such as administrative data and medical records. Therefore, the outcome of interest has already occurred (or not) by the time the study is started.
Case-control studies are considered the highest quality of retrospective study because they try to approximate a control or comparison group. In our study, claim information would be collected on the population at risk: workers with low-back pain. They would be divided into two groups. The first group would be the control group, those who did not return to work. The second group would be the case group, those who did return to work. Claim information for workers who underwent physiotherapy might be compared to claim information on those who did not (the control group).

In adherence to the federal guidelines the College defines all prospective studies as systematic research. All prospective studies must be approved by the IRB with the exception of those that fall into the exempt category as detailed in Section 2.3.3. Retrospective studies with one, two, or three subjects are not considered systematic research and are therefore not subject to IRB review. Nonetheless, investigators must file for an exemption for IRB review as detailed in Section 2.3.3.

### 3.2 Researchers and Research Staff

#### 3.2.1 Investigator Classifications

Faculty or staff members at the College may serve as the Principal Investigator or as the faculty sponsor on a research project involving human subjects. Adjunct faculty of the institution and any investigator whose status is considered to be “in training” (i.e., students or residents) may not serve as a Principal Investigator, but may serve as a co-investigator.

The IRB recognizes one principal investigator for each study. The principal investigator has ultimate responsibility for the research activities. Protocols that require skills beyond those held by the principal investigator must be modified to meet the investigator's skills or have one or more additional qualified faculty as co-investigator(s).

The research team consists of the principal investigator and other individuals (also known as key personnel) who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol. The research team also consists of individuals who intervene or interact directly with human subjects (including the recruitment or consenting thereof) or who analyze data and/or tissue derived from humans for the purposes of the research program.

The principle investigator is ultimately responsible for the conduct of research. Investigators are able to delegate research responsibility; however they must maintain oversight and ultimate responsibility for the conduct of those they delegate responsibility. The principal investigator and his/her research staff are expected to follow the College’s policies addressing the disclosure of conflicts of interest as described in the Financial Conflict of Interest Form and the policies referenced therein. Disclosures of potential conflicts of interest are reviewed and resolved by the
IRB. The IRB has the final authority to decide whether the potential conflict of interest and its management, if any, allows the research to be approved.

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.

The College employs the Collaborative Institutional Training Initiative (CITI) course as its training program. Required CITI training for investigations includes, but is not limited to, modules on the history and ethical principles of human subject research, basic IRB regulations and review process, informed consent, and research with vulnerable participants. The College requires a refresher training course to be completed every two years.

Completion of the required training is a condition for IRB approval of protocols and release of funds, regardless of the project’s source of funding. During the review the IRB evaluates whether these requirements are met for each protocol event (new protocol, modification and continuing review).

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).

3.2.2 Investigator Conflict of Interest

All investigators participating in research at the College have a primary obligation to conduct the research free of the appearance of conflict. To participate in research that might be perceived to be compromised due to a personal or institutional interest is contrary to this commitment unless the conflict of interest is managed or eliminated. Under certain circumstances, an investigator’s personal interest might be too significant to permit participation in the research. The Conflicts of Interest Policy of the College followed that of the Research Foundation for the State University of New York and follow current federal and state regulations designed to protect the integrity of funded research. All investigators and key research personnel must follow the Conflicts of Interest policy of the College to preserve public trust in the integrity and quality of research at the College by minimizing actual or perceived conflict of interest in the conduct of research.

A conflict of interest occurs when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results or reporting of
research activities or findings. This can include an ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a non-publicly traded corporation), or any equity interest in a publicly traded corporation during the time the investigator is carrying out the study and for 1 year following completion of the study. A conflict of interest can also include compensation made by an organization to the investigator or the institution exclusive of the costs of conducting the research during the time the investigator is carrying out the study and for 1 year following the completion of the study. This includes, but is not limited to:

- Income from seminars, lectures or teaching engagements.
- Income from service on advisory committees or review panels.
- Grants to fund ongoing research.
- Compensation in the form of equipment.
- Retainers for ongoing consultation.

Non-financial conflict of interest may exist when an individual serves dual roles, such as health care provider and investigator. Other interests such as publication, promotion or tenure, can also become conflicts of interest that may affect an individual's judgment. Membership in oversight committees such as the IRB as well as positions of authority may pose potential conflicts of interest. Any position that includes responsibilities for the review and approval of research projects or contracts other than his/her own may potentially affect the design of, decisions made and/or action taken surrounding a specific study.

### 3.2.3 Individual Conflicts of Interest

Both financial and non-financial conflicts of interest and are guided by Code of Federal Regulations [Title 42 of the Code of Federal Regulations (CFR) Part 50 Subpart F] that promotes objectivity in research to ensure conflict of interests do not adversely affect the protection of participants or the credibility of the College HRPP. For clinical studies involving the use of new human drugs and biological products or medical devices, certifications and disclosure requirements are defined in Food and Drug Administration (FDA) regulations, Title [21 CFR Part 54].

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively disclosed and managed when they cannot be eliminated. The Conflicts of Interest in Research Policy identifies procedures for disclosure, evaluation and either management or elimination of potential conflicts of interest in research. Under the Conflicts of Interest in Research Policy, a conflict of interest may exist whenever an investigator has a financial interest in a research project, including any interest in entities sponsoring or otherwise affected by the research and any interests in products being used.
in the research. When the interest is considered minor, the investigator’s participation in the research will normally be permitted, subject to a conflict of management plan issued by HSCC. When an interest is significant, an investigator will not normally be permitted to participate in the research, unless the Associate Dean and the HSCC concur that compelling circumstances exist to merit an exception to the policy and a conflict management plan is adopted to maintain research integrity and serve the best interests of subjects enrolled in the research.

Under the Conflict of Interest in Research Policy, all investigators and other key research personnel must make protocol-specific financial interest disclosures for every research project, regardless of subject matter or funding. Investigators and other key research personnel include all of those individuals who do any of the following things in connection with research at the College:

- Design, conduct or direct the research.
- Apply for grants or awards to perform research.
- Serve as a principal investigator, co-investigator or sub-investigator.
- Enroll subjects into the study.
- Obtain consent from human subjects.
- Make decisions related to eligibility of human subjects.
- Analyze, report, present or publish research data.

In addition, all such individuals must complete and return an annual Conflict of Interest disclosure form as part of the Research Authorization Form (RAF) under which they disclose any outside interests related to their responsibilities at College. For an individual research project, in the event the investigator or key personnel (or any of their immediate family members) has a financial interest in the protocol, the investigator is required to submit additional information as requested by the HRCC. The HRCC will review the disclosures, together with the protocol and any proposed conflict management plan, and will determine if the disclosed financial interest is a significant financial interest which needs creation of a conflict management plan. The HRCC in consultation with the Associate Dean will review and evaluate the matter to determine whether compelling circumstances exist to justify participation in the research notwithstanding the disclosed financial interest. If so, the HRCC issue a conflict management plan to be reviewed and approved upon by the investigator with the conflict and the principal investigator for the project. Based on the significance of the interest and the conflict and the potential for adverse effects on the protection of subjects, conflict management plans issued by the HRCC can include:

- Reduction, divestiture or elimination of the disclosed financial interest.
- Disclosure to subjects through the consent process.
- Disclosure to the research sponsor, to public officers and to other investigators.
- Modifications in the research plan.
- Restrictions on the investigator’s participation in the research.
- Monitoring by independent reviewers.
• Appointment of a non-conflicted principal investigator.

Where HRCC determines that compelling circumstances do not exist to justify participation in the research, the investigator with a disclosed financial interest will not be permitted to participate in the conduct of the research at the College. For all human research projects where an investigator discloses a financial interest, the IRB will not issue its final approval of any project before the HRC has completed its review and evaluation of the potential conflict. Upon completion of its review and evaluation, the CMU will notify the IRB of the final determination of the conflict of interest review and, if applicable, will submit to the IRB the conflict management plan issued by the CMU or the RCOIC and approved by the applicable investigators.

Upon receipt, the IRB Chair (or designee) will review the conflict management plan issued by the HRCC and reports the results of the evaluation of management plan to the convened IRB. The IRB may accept or modify the plan indicated by the HRCC in order to protect research subjects. The completion of the review will be documented in the IRB’s protocol file. A copy of the final, approved conflict management plan will be presented to the principal investigator.

If an investigator’s financial interests in a research protocol changes during the course of a study, the investigator is required to submit a revised Investigator Financial Interest Disclosure Form to the HRCC Chair and Associate Dean and not wait for the annual disclosure. The HRCC will review the change to determine if any conflict management plan on file is adequate and appropriate for the changed circumstances. If so, procedures will be followed as described above.

3.2.4 Institutional Conflict of Interest

Under the College Institutional Conflicts Policy, an institutional conflict of interest (ICOI) arising in human subjects’ research when a financial interest of the College may affect or appear to affect the design, conduct, reporting, review, or oversight of human subject’s research. An ICOI is of significant concern when the College’s interests create the potential for inappropriate influence over the research project, particularly to the integrity of the research and the safety and care of patients enrolled in the research. All potential ICOI requires disclosure, evaluation and either management or elimination.

An ICOI is deemed to arise whenever the College receives or might reasonably be expect to receive royalty income from the sale of a product covered by a College intellectual property right being used in human subjects research or holds equity interests acquired in the College’s technology licensing activities (or investments related to such activities) in the research sponsor.

As a matter of policy, the College will not participate in a human subjects’ research project when an ICOI is deemed to arise due to such institutional interests. An exception may only be made if the
Associate Dean or HRCC determines that compelling circumstances exist to merit an exception and a conflict management plan is adopted. The conflict management plan can include the restrictions contemplated for individual conflict management plans as outlined above and additional restrictions on the College’s institutional participation in the research. For all human subjects’ research projects where an ICOI exists, the IRB will not issue its final approval of any project before the HRCC has completed its review and evaluation of the ICOI. The IRB may not approve research protocols referred to the HRCC that have not been reviewed by the HRCC. Upon completion of its review and evaluation, the HRCC will notify the IRB Chair of its final determination of the review and, if applicable, will submit to the IRB the conflict management plan issued by the HRCC and approved by the applicable investigators. Upon receipt, the IRB Chair will review the conflict management plan issued by the HRCC prior to issuing the IRB’s final approval of the project. The IRB may modify the plan to impose more stringent restrictions than those imposed by the HRCC in order to protect research subjects. A copy of the final, approved conflict management plan will be presented to the Associate Dean and the principal investigator.

3.3 Protocol Development

When developing a protocol, the principal investigator or a member of the protocol research team may contact the IRB Chair for a determination whether the proposed project constitutes human research, and if so, what level of review would be required. Contact with the IRB Chair should be made by email and must include a brief description of the proposed research. The IRB Chair will respond to the principal investigator or member of the research team by email. In the application form for IRB review uploaded to IRBnet, the investigator must answer all questions and make sure that consent information is in agreement with the research plan. The proposed consent/assent form (if applicable) must include or address:

- The general principals and basic elements of informed consent.
- The original and translated consent documents, as necessary, considering likely subject population(s).
- College and IRB-approved formats for consent forms and assent forms.
- Any waiver of consent conditions.

Following institutional regulatory committee review and sign-off, the investigator must submit protocol and all attachments to departmental IRB reviewer, if applicable. If the proposed research is DHHS-sponsored, application materials must include the entire sponsoring application. If there is a significant variation between the DHHS application and the IRB protocol, the investigator must identify and justify the discordance. If research is FDA-regulated and industry-sponsored, materials delivered to the IRB must include the entire sponsor's protocol as well as, for drug studies, the investigator's brochure [21 CFR 312.23(a)(5) and 312.55], FDA form 1572, and the sponsor Financial Disclosure form.
The significance of the research depends upon the validity of the results. It is unethical to put subjects at risk or to inconvenience them through participation in a study that may produce little or no reliable information. Regardless of the source of funding, it is the principal investigator’s responsibility to judge the research design to be sound enough to meet its objectives before submitting the protocol for IRB review. In developing, or in evaluating the adequacy of, a research design involving investigational drugs or biological products, the investigator should refer to the FDA Guidance Documents representing the Agency's current thinking on good clinical practice and the conduct of clinical trials and selected guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Investigators may ask for a preliminary review of the application before uploading it to IRBnet by contacting the IRB Chair.

The investigator should also be familiar with the various types of control groups, their relative advantages and disadvantages, and the ethical issues associated with each control type, as outlined in the FDA guidance Choice of Control Group and Related Issues, published May 2001. Although directly applicable to FDA-regulated trials involving investigational drugs or biological products, many of the principles can be applied to clinical trials in general.

### 3.4 Human Research Protection Resources

Principal investigators are required to indicate in their IRB applications whether they will have access to adequate resources to carry out the research. Resources, including space, personnel, services and equipment required for conducting the proposed research properly and safely, must remain available as needed throughout the research. The investigator must provide information about the qualifications and number of study staff, personnel training, available facilities, and the time available to conduct and complete the research, and must demonstrate sufficient access to a population allowing recruitment of the required number of participants. Investigators must continually monitor the resources allocated for their research and notify the IRB if any change in the availability of resources may adversely impact the rights and welfare of participants. In addition to administrative and IRB approvals of a research study, sponsored human participant research cannot begin until a contract with the sponsor has been finalized or a grant award activated.

### 3.5 Recruitment and the Consent Process

Researchers and their staff recruit must participants in a fair and equitable manner as described in Section 1. Informed consent is a continuing process whereby the investigator and research participant have an on-going dialogue about all aspects of a research study that might inform a participant’s decision to take part in the study, and their decision to continue their involvement as a participant. Although consent is given it may be withdrawn at any point. The informed consent process should be regarded as continuing throughout the duration of the research. The purpose of
the consent process is to assure knowledgeable decision-making and voluntary participation.

3.5.1 Subject Recruitment
Investigators are responsible for recruiting research subjects in a manner that is fair, ethical and equitable. IRB approval is required for all recruitment procedures and materials. Recruitment materials must be consistent with the approved IRB protocol, accurate, and not coercive. For specific information regarding recruitment materials, review and creation guidance, please see the Informational Sheet regarding Advertisements and Recruitment Materials.

3.5.2 Recruitment Incentives
Payment arrangements among sponsors, organizations, investigators, and those referring research participants may place participants at risk of coercion or undue influence or cause inequitable selection. Payment in exchange for referrals of prospective participants from researchers (e.g., finder’s fees) is not permitted. Similarly, payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (e.g., bonus payments) are also not permitted.

3.5.3 Payment to Subjects
Payment to research subjects may be an incentive for participation or a way to reimburse a subject for travel and other experiences incurred due to participation. However, payment for participation is not considered a research benefit. Regardless of the form of remuneration, investigators must take care to avoid coercion of subjects. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation. The amount of compensation must be proportional to the risks and inconveniences posed by participation in the study. Investigators who wish to pay research subjects must indicate in their research project application the justification for such payment. Such justification should:

- Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the subject.
- State the terms of the subject participation agreement and the amount of payment in the informed consent form.
- Substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure on the veteran patient to volunteer for the research study.

The IRB must review both the amount of payment and the proposed method of disbursement to assure that neither entails problems of coercion or undue influence. Credit for payment should
accrue and not be contingent upon the participant completing the entire study. Any amount paid as bonus for completion of the entire study should not be so great that it becomes coercive.

The IRB prohibits:

- The entire payment being contingent upon a subject’s completion of the entire study.
- Compensation for participation in a trial offered by a sponsor from including a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
- Payments to the organization or research staff designed to accelerate recruitment that are tied to the rate or timing of enrollment.

The consent form must describe the terms of payment and the conditions under which subjects would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed). Unless the study is confidential, the College requires identifying information to issue checks, cash, or gift certificates to subjects. The consent form must inform subjects that they will be asked to provide their social security number and verification of U.S citizenship or permanent resident status to receive payment. For confidential studies only name and address are required, but the principal investigator must keep an identity key in a secure place.

The principal investigator is responsible for obtaining and documenting the informed consent of individuals who participate in research, unless the requirement to obtain and document informed consent is altered or waived by the IRB. The IRBNet provides consent form templates, which address the required elements of informed consent, as well as providing language for other situations, in which certain additional information may need to be disclosed to participants.

In the application for IRB approval, the principal investigator must:

- Describe the consent process in enough detail to allow for meaningful review by the IRB.
- Include the proposed written informed consent document(s) that address(es) each of the elements of informed consent in the context of the research (unless the IRB waives the documentation requirement).
- Include any written material to be given to prospective participants to explain the nature of the research.

The principal investigator is responsible for making all revisions to the proposed consent document as requested by the IRB. Any other change to the consent document must be submitted to the IRB for prior review and approval. No research procedures, including screening procedures to determine if an individual is eligible to enroll in the research, may begin until after the participant has signed the consent form, unless the IRB has approved a waiver or alteration of consent. Retroactive consent (i.e., consent obtained or documented after the participant has
undergone one or more research procedures) is not acceptable.

The principal investigator may delegate all or a portion of the informed consent process to others on the research team, such as co-investigators or research coordinators. However, it is ultimately the responsibility of the principal investigator to ensure that those individuals carry out their tasks properly and in accordance with regulatory and IRB requirements. The principal investigator must use the consent document currently approved by the IRB. The IRB approval date must appear on the signature page of the consent document.

No participants can be involved in research prior to the IRB approval date, and no participants should be involved in research using a consent document whose approval period has expired. The principal investigator or his/her delegate is responsible for giving the participant a copy of the signed informed consent document, and for maintaining the original form.

3.6 Requests for Information

The principal investigator and members of the research staff are required to respond promptly and adequately to all requests for information received from participants, prospective participants and their family members or designated representatives. In addition to providing information and answering questions that arise as part of the informed consent process, the principal investigator must inform the participant that he/she is available to answer any questions that arise about the research in the future. The consent form must list the full name and contact information for the principal investigator, and other research study staff as appropriate. The consent form must also inform participants how to reach the IRB if they have any questions about their rights as research subjects.

3.7 Complaints

The principal investigator is expected to investigate and respond promptly to complaints, and to follow the proper procedure for addressing and reporting complaints to the IRB. A complaint is a formal or informal, written or oral, expression of dissatisfaction by the participant or the participant’s representative. Complaints that are not resolved promptly by the PI or member of the research staff must be reported to the IRB as follows:

- Complete and submit a Report Form to the IRB.
- Include with the Report Form a brief description of the complaint and the circumstances in which the complaint was made and any action taken to date in addressing the complaint.

If the complaint is not directly related to the conduct or design of the research, the IRB staff may
refer the complaint to the Associate Dean or HRCC Chair. In circumstances in which the complaint is referred, the IRB staff should provide the participant with the name and contact information for the referral.

At the annual continuing review, investigators are required to list all complaints received about the research in the past year, whether or not they were previously reported to the IRB. If the complaint involves the College’s privacy practices, all documentation relating to the complaint must be retained for at least six years from the date of creation.

3.8 Research Oversight

The principal investigator is responsible for ensuring recruitment activities, whether undertaken by research staff or the principal investigator, are via methods set forth in the protocol application and approved by the IRB. The investigator must ensure that informed consent is obtained from each research participant before that individual participates in the research study. The investigator may delegate the task of obtaining informed consent to another individual knowledgeable about the research, while retaining ultimate responsibility over the conduct of the study.

The principal investigator must ensure selection of study participants is equitable and appropriate to the goals of the study. Adequate safeguards for the protection of participants during the recruitment and conduct of research must be set forth in the protocol application. Investigators are responsible for assuring the quality of the informed consent process and for making sure that consent is obtained and documented before subject participation, unless waivers are granted by the IRB.

3.8.1 Study Conduct

The principal investigator is responsible for conducting the study in a manner that is scientifically and ethically sound and for ensuring the use of appropriate methods and correct procedures, according to the approved protocol. Any new information, modification, or unanticipated problem involving risks to participants or others must be promptly reported to the IRB, and research participants must be informed of any change that may affect their willingness to participate.

The investigator must assure that all personnel under his or her supervision are adequately trained and supervised and that research duties are delegated to individuals qualified to perform the assigned tasks. Any non-compliance must be reported promptly to the HRCC.

The principal investigator is also responsible for the timely and proper administration of the research project. Beyond the scientific and clinical conduct of the study, responsibilities include:
• Compliance with federal, state, and local laws and College policies, including disclosure of any potential conflict of interest.
• Adhering to the respective institutional code of conduct.
• Fiscal management of the project.
• Training and supervision of postdoctoral candidates, students, and residents.
• Compliance with the sponsor’s terms and conditions (e.g., non-disclosure of sponsor confidential information).
• Submission of all technical, progress, financial, and invention reports on a timely basis,
• Submission of modification and continuing review applications in a timely manner.
• Obtaining approval for changes prior to implementation.

3.8.2 Compliance with the IRB

Federal regulations require that any research study involving human subjects be reviewed and approved by an IRB. IRB approval must be obtained before any recruitment or screening can take place. It is the principal investigator’s responsibility to submit a written protocol to the IRB for review. At submission, the obligations of the principal investigator with respect to oversight of their research protocols and research staff during recruitment, selection of study participants, and conduct of the study according to the protocol as approved by the IRB are stated on IRBNet and must be agreed to by the principal investigator for the submission to be accepted. The principal investigator is responsible for ongoing adherence to the determinations and requirements of the IRB for the duration of the research. In addition to IRB approval, investigators must submit a Research Authorization Form and Conflict of Interest Forms for all personnel to the Associate Dean or GCVR office. Even with IRB approval, studies may not commence until the Research Authorization Form is approved by appropriate administrators.

Principal investigators must submit protocols for annual continuing review by the IRB before the expiration date of the protocols, and in sufficient time to ensure the non-interruption of studies. At the conclusion of the study, principal investigators involved in research approved under regular review must submit a final report to the IRB within thirty days. If this is not done, a memorandum is sent by the IRB Chair to the Associate Dean for potential disciplinary action.

3.9 Responsibility of Investigators Conducting IRB-Approved Activities

Once his/her project is approved by IRB, the investigator must:
• Conduct every aspect of the project as approved by IRB.
• Promptly report any revisions or amendments to the research activity for review and approval by IRB 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 IRB 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.

3.10 Confidentiality of Records and Personal Data

Principal investigators working with human subjects must safeguard the privacy of participants and protect the confidentiality of personal information:

- Safeguard mechanisms must be established, maintained, and documented throughout the research process.
- Sustained attention must be paid to maintaining confidentiality of research data in the design, implementation, conduct, and reporting of research.
- Full information about the privacy and confidentiality of data must be provided to prospective participants through the informed consent process.
- Unintentional breaches must be avoided by taking additional precautions in communication, administration and storage of information.

3.11 Volunteer and Trainee Policies

All volunteers and trainees are required to complete a volunteer registration form clearly stating the purpose, for which they are at the College, the activities in which they will be engaged while at the College, and the anticipated length of their visit. The form must be approved by the volunteer’s designated primary supervisor and the Associate Dean. The completed form will then be sent to Human Resources who will issue an appointment letter. The volunteer will be issued a temporary identification card from the College Police. Volunteer status is limited to one year.

Prior to undertaking laboratory activities, volunteers and trainees must attend and complete all appropriate training. These may include research ethics training for working with human subjects, appropriate training for working with non-human species, safety training, hazardous chemical training, etc. Volunteers and trainees may not work with human subjects or patient records without
the prior approval of the IRB. The principal investigator is required to include the names, qualifications and activities of all volunteers and trainees in his or her animal protocol form, along with a description of the activities that the volunteers and trainees will perform on animals.

Volunteers and trainees may not perform work that would otherwise be performed by a College employee, and the donated services may not be considered compensable work. All volunteers and trainees are subject to College policies and procedures, as well as applicable federal, state and local laws that may apply to their activities.
4. Health Insurance Portability and Accountability Act (HIPAA)

4.1 Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the creation of a Privacy Rule for identifiable health information. The resulting Privacy Rule, finalized in August 2002, set a compliance date of April 14, 2003. The objective of the rule is to protect the privacy of an individual's health care information. It creates a federal "floor" of protection so that every person in this country has at least the same basic rights and protections, though some may have additional rights depending on state law. While the main impact of the Privacy Rule will be on the routine provision of and billing for health care, the Rule will also affect the conduct and oversight of research. Researchers, IRB staff and members as well as research administration must be aware of these changes.

Protected Health Information (PHI) obtained by College faculty or staff may not be used internally or disclosed to any outside person or organization for research purposes without prior approval of the IRB. College researchers must also abide by all HIPAA policies regarding privacy and security. HIPAA is an expansive federal law, only part of which is intended to protect the privacy of health care information. HIPAA required Congress to enact a health information privacy law by August 1999 and stated that if it did not act by then, which it did not, the U. S. DHHS must develop privacy regulations.

4.2 Effects of HIPAA on Research

The final Privacy Rule published on August 14, 2002 included a number of changes in how the Rule applies to research. See the NIH HIPAA Privacy Rule Booklet for Research and the NIH fact sheet on Institutional Review Boards and HIPAA for more information on how HIPAA applies to research. See also Impact of the Privacy Rule on Academic Research, a white paper published by the American Council on Education.

The College is a covered entity under HIPAA. Researchers who are working with “Protected Health Information” (PHI) are required to comply with the rules on HIPAA. The College IRB acts as the Institution’s Privacy Board. The Privacy Rule permits covered entities to use or disclose protected health information for research purposes when the individual who is the subject of the information authorizes its use or disclosure. For clinical trials, authorization must be sought in addition to informed consent. Authorization must also be sought for other research uses or disclosures of protected health information that do not qualify for an IRB waiver of authorization.
The Privacy Rule has several special provisions that apply to research authorizations for uses and disclosures of PHI for research purposes. These requirements are as follows:

- An authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the end of the research study.
- An authorization for the use or disclosure of protected health information for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study (except for research involving the use or disclosure of psychotherapy notes, which must be authorized separately).
- Research authorization forms must be filled out completely and accurately by the investigator, to ensure that all parties who require access to protected health information for the research (including sponsors, IRBs, etc.) are identified in the form and may receive the information.

4.3 Research under HIPAA

HIPAA defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." This definition is identical with the one used in the “Common Rule”, a separate federal legislation designed to protect human subjects involved in research. HIPAA describes privacy standards for protecting PHI and so only applies to research that involves humans’ (not animals’) health information.

4.4 Waiver of Authorization for Use or Disclosure of Protected Health Information in Research

Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances. A covered entity may use or disclose protected health information for research when presented with documentation that an IRB has granted a waiver of authorization [see 45 CFR 164.512(i)(1)(i)]. This provision of the Privacy Rule might be used, for example, to conduct records research, epidemiological studies, or other research where de-identified data is unavailable or not suited to the research purpose.

The waiver documentation presented to the covered entity must include the following:

- Identification of the IRB and the date on which the alteration or waiver of authorization was approved.
- A statement that the IRB has determined that the alteration or waiver of authorization, in whole or in part, satisfies the three criteria in the Rule.
• A brief description of the protected health information for which use or access has been determined to be necessary by the IRB.

• A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures.

• The signature of the chair or other member, as designated by the chair, of the IRB.

The following criteria must be satisfied for the IRB to approve a waiver of authorization under the Privacy Rule. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

• An adequate plan to protect the identifiers from improper use and disclosure.

• An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

• Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.

• Description that the research could not be conducted practicably without the waiver or alteration.

• Description that the research could not be conducted practicably without access to and use of the protected health information.

4.5 Review Preparatory to Research

The Privacy Rule permits a covered entity to use or disclose protected health information to a researcher without authorization or waiver for the limited purpose of a “review preparatory to research.” Such reviews may be used to prepare a research protocol, or to determine whether a research site has a sufficient population of potential research subjects. Prior to permitting the researcher to access the protected health information, the covered entity must obtain representations from the researcher that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any protected health information from the covered entity, and that protected health information for which access is sought is necessary for the research purpose. Researchers should consult the covered entity regarding any forms or applications necessary to conduct a review preparatory to research.

Researchers conducting a review preparatory to research may not record information in identifiable form, nor may they use the information that they receive to contact potential subjects, unless the investigator is also the subject’s treating physician. Because the Privacy Rule permits a covered
entity to disclose protected health information to the individual who is the subject of the information, covered health care providers and patients may continue to discuss the option of enrolling in a clinical trial without patient authorization. Even when permitted by the Privacy Rule, however, any use of patient information for recruitment must comply with IRB recruitment policies:

- All human subjects’ research requires IRB review to determine either exempt status or need for further review.
- Reviews preparatory to research that are permitted under HIPAA may or may not be human subjects’ research depending on the investigation being conducted.
  - Only those reviews of a database by an individual entitled to access that database intended to enumerate an available data set without reviewing PHI and for which no PHI is recorded do not require review. IRB review is required for all other uses of PHI as indicated.
  - If the research involves a de-identified data set, defined as removing the following identifiers, then a de-identified data set certification form must be completed submitted for administrative review and certified prior to accessing the data set. This activity also requires an IRB determined exemption from review:
    - Names
    - Geographic information including city, state, and zip code
    - Elements of dates (except years)
    - Telephone numbers
    - Fax numbers
    - E-mail addresses
    - Social Security numbers
    - Medical record and prescription numbers
    - Health plan beneficiary numbers
    - Account numbers
    - Certificate and license numbers
    - VIN and license plate numbers
    - Device identifiers and serial numbers
    - Web URLs and IP addresses
    - Biometric identifiers such as finger prints.
    - Full face and comparable photo images
    - Any other unique identifying numbers

IRB review and approval is required prior to initiating this research. Investigators are not authorized to contact potential research subjects identified in reviews preparatory to research unless they are directly responsible for care of the potential subject and entitled to PHI as a result of that duty.
Investigators who have previously obtained full consent and authorization to contact a research subject as a result of a previously approved research project may contact his or her former research subjects provided that the subject agreed to be contacted for information on future research conducted by the same principal investigator or co-investigator(s).

4.6 Research on Protected Health Information of Decedents

The protections of the Common Rule apply only to living human beings; by contrast, the Privacy Rule also protects the identifiable health information of deceased persons (“decedents”). The Privacy Rule contains an exception to the authorization requirement for research that involves the protected health information of decedents. A covered entity may use or disclose decedents’ protected health information for research if the entity obtains representations from the researcher that the use or disclosure being sought is solely for research on the protected health information of decedents, that the protected health information being sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is being sought. Researchers should submit the applicable IRB form for IRB approval when they intend to conduct research involving decedents’ protected health information.

4.7 Limited Data Sets with a Data Use Agreement

When a researcher does not need direct identifiers for a study but does require certain data elements that are not permitted in de-identified data, the Privacy Rule permits a covered entity to disclose a “limited data set” to the researcher without authorization or waiver, provided that the researcher has signed a data use agreement. The limited data set is still considered to be protected health information, but it must exclude only specified direct identifiers of the individual or of relatives, employers, or household members of the individual.

If the research involves a limited data set, defined as removing the following 18 identifiers:

- Names
- Geographic information including city, state, and zip code
- Elements of dates (except years)
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social Security numbers
- Medical record and prescription numbers
- Health plan beneficiary numbers
- Account numbers
• Certificate and license numbers
• VIN and license plate numbers
• Device identifiers and serial numbers
• Web URLs and IP addresses
• Biometric identifiers such as fingerprints.
• Full face and comparable photo images
• Any other unique identifying numbers

The Privacy Rule requires that the data use agreement used in conjunction with the limited data set contain provisions that:

• Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Rule if done by the covered entity.
• Limit who can use or receive the data.
• Require the recipient to agree to the following:
  o Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law.
  o Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement.
  o Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware.
  o Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set.
  o Not to identify the information or contact the individual.
• Researchers who will be receiving limited data sets must submit a signed copy of the covered entity’s data use agreement to the College IRB for approval, prior to initiating the research.

4.8 Transition Provisions

The Privacy Rule contains certain grandfathering provisions that permit a covered entity to use and disclose protected health information for research after the Rule’s compliance date of April 14, 2003, if the researcher obtained any one of the following prior to the compliance date:

• An authorization or other express legal permission from an individual to use or disclose protected health information for the research
• The informed consent of the individual to participate in the research
• An IRB waiver of informed consent for the research
Even if informed consent or other express legal permission was obtained prior to the compliance date, if new subjects are enrolled or existing subjects are re-consented after the compliance date, the covered entity must obtain the individual's authorization. For example, if there was a temporary waiver of informed consent for emergency research under the FDA’s human subject protection regulations, and informed consent was later sought after the compliance date, individual authorization must be sought at the same time. The transition provisions apply to both uses and disclosures of protected health information for specific research protocols and uses or disclosures to databases or repositories maintained for future research.

4.9 HIPAA and Document Requirements

HIPAA documents include an authorization form, a waiver of authorization form, limited data set form, and a de-identification form. One of these documents must be used whenever PHI is utilized in the research.

4.10 Patient Rights and Research

Under HIPAA, patients have certain rights. Those that may affect research include the right to receive a Notice of Privacy Practices, the right to access, inspect, and receive a copy of one's own PHI, the right to request an amendment to one’s own PHI, and the right to an accounting of certain disclosures of PHI that occur outside the scope of treatment, payment and health care operations that have not been authorized.

4.11 HIPAA and Existing Studies

Any research subject enrolled in a study that uses PHI from a covered entity must sign a HIPAA-compliant authorization form. This form is in addition to the existing Informed Consent document, and is federally required. In a few cases, the Informed Consent document may be combined with a HIPAA authorization.

4.12 Waivers to HIPAA Consent Form

In some cases the College IRB may approve a waiver to use of the HIPAA authorization form. This may occur when the IRB finds that the research could not be practically done without the waiver, and not without access to and use of the PHI, and that disclosure poses minimal risk to privacy.
4.13 Institutional Policy for the Use of Patient Information

All patients examined and treated within the UEC are required to sign the “Consent for Examination and Treatment”. The consent contains the following wording relevant to the use of patient data: “I authorize the UEC to retain, for scientific or educational purposes, or to otherwise utilize, photographs, videotape or other images or clinical information from the procedure, examination or treatment consistent with college policies and HIPAA regulations for patient privacy protection and research.”

The UEC owns and maintains all patient information and data (records, images, etc.) collected in the clinic. The UEC abides by and enforces regulations covered by the HIPAA, which includes policies on the use of PHI for the protection of patient privacy. These policies can be found in the UEC Policy and Procedure Manual (see policies C-13, C-19, D-6, H-4, H-5, L-3, M-11, N-1, R-7, and S-17).

Faculty and staff wishing to use data or images from UEC patients or their records for anything other than internal educational purposes (SUNY and UEC) must either receive research authorization with IRB approval or submit a statement of intent prior to the use of any other patient information to the UEC Compliance Officer.

The use of patient data for research is exempt from UEC oversight, but must follow institutional research policies. No human subject research is ever permitted without an approved Research Authorization Form and Institutional Review Board approval. Record reviews and case studies of more than three patients are considered to be research and subject to institutional research policies for human subject research. Any question concerning human subject research compliance should be directed to the Associate Dean of Graduate Studies and Research.

With the exception of authorized research and for purposes of internal education, the use of UEC patient data (including de-identified data) for any type of presentation, publication, or commercial application (including case studies, and continuing education presentations), is not permitted without prior notification of intent to the UEC Compliance Officer. Any questions should be directed to UEC Compliance Officer or the Vice President of Clinical Affairs.

Before the use of any patient information, faculty and staff must provide written notification of intent prior to using the data to the UEC Compliance Officer. This notification identifies the patient(s) involved, and provides a concise and specific statement of why the data are needed, how they will be used, and where they will be presented or published. Any commercial or financial interest must be disclosed. A copy of the final presentation, publication, or link to the use of the data must be provided. The UEC Compliance Officer may disallow any use of patient data by notifying the faculty and will maintain records of for at least three years. Violations of the policy may result in disciplinary actions including restriction of privileges.
5. Special Topics

5.1 Blood Draws for Human Subject Research
As a general rule, investigators must not draw more blood from any research subject than is needed to answer the research question, and should design the research to minimize that volume.

5.2 Blood Drawing Limits for Protocols Reviewed Using the Expedited Procedure
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- From healthy, non-pregnant 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.
- From other adults and children, 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.

5.3 Blood Drawing Limits for Protocols Reviewed by the IRB
The convened IRB may approve a volume of blood drawn for research purposes that exceeds the limits referred to above. As a general rule, blood drawn for research purposes must not exceed the following volumes:

- For an adult, the amount of blood that may be drawn for research purposes shall not exceed 5 ml/kg in any one 24 hour period, and 7 mL/kg in any eight week period. Any exception to these limits must be specifically justified in the research protocol and approved by a convened IRB.
- For a child, the amount of blood that may be drawn for research purposes shall not exceed 3 ml/kg in any 24 hour period, and 7 mL/kg in any eight week period. Any exception to these limits must be specifically justified in the research protocol and approved by a convened IRB.

5.4 Exceptions to Blood Drawing Limits
For any subject whose clinical condition might be adversely affected by removal of the
volumes stated above, for example, a person with significant anemia or compromised cardiac output, investigators should further limit the volume of blood withdrawn for research purposes so as to minimize harm to the subject.

A subject’s attending physician may determine if phlebotomy for research purposes should be further restricted below the limits stated above. Also, the convened IRB in its review of a specific protocol may limit the blood volumes to be obtained for research to amounts lower than the upper limits provided above. Exceptions shall not be permitted for phlebotomy intended solely for research purposes unless the limits have been explicitly increased in a research protocol that has received approval by a convened IRB.
Congratulations, you have taken the first step toward seeking out and administering funds in support of your innovative and exploratory concepts! Your ideas and work will enhance the academic, commercial, and/or social communities in New York and around the globe.

The *Principal Investigator Handbook*’s primary goal is to help any Project Manager (PM), Principal Investigator (PI) or project staff to navigate the grant process from application to close-out of an award administered by The Research Foundation for The State University of New York (RF).

While the RF is the legal recipient of the award on behalf of the campus, YOU are accountable for the proper fiscal management and conduct of the project. If you fail to abide by the policies of the RF, the campus, or the sponsor, you may be held liable. The RF’s central mission is to ensure that each PM, PI or anyone assisting those individuals has the necessary tools at his/her disposal to manage a successful project.
Using this Handbook

The structure of the *PI Handbook* replicates the lifecycle of your idea from concept to award close out. This handbook is not intended as a complete guide to grant application or sponsored program (SP) administration, but a guide to help you, the investigator, understand the most fundamental processes that affect the life of a sponsored project and direct you to the appropriate resource for your situation.

The reference materials provide concise explanations of the most common questions and issues. This guide will not explain every step or nuance involved in administering a sponsored project. This handbook provides links to important and detailed information to help you comply with federal and organization rules and regulations.

To mitigate any omissions of detail from the document, a few other additional items have been included:

- **Interactive appendix** – links to commonly referenced policies and procedures that govern sponsored research in both the RF/SUNY system and the federal government
- **Glossary of Acronyms and Terms** – a dictionary of sorts, defining common sponsored program, SUNY, and RF terms you may encounter while performing sponsored project administration
- **OMB Circulars** – information and link

Do not hesitate to contact your Sponsored Programs office should you need assistance in any phase of your project.

Campus Research/Sponsored Program Office Contacts

For you, the Principal Investigator, the first point of contact should be your campus’ Research and/or Sponsored Programs office.*

- Connect with your campus office from the [Campus PI Web Sites](#) page after logging into the RF PI intranet.
- All main campus links can be found on the RF website, under Contact RF > [Campus Locations](#).

*Office names vary by campus.*
The RF/SUNY Relationship and You

The RF was founded in 1951 to serve SUNY and to capitalize on its scope, scale and diversity as an engine of New York’s innovation economy.

The largest, most comprehensive university-connected research foundation in the country, the RF supports nearly $1 billion in SUNY research activity annually, providing sponsored programs administration and innovation support services to SUNY faculty performing research in life sciences and medicine; engineering and nanotechnology; physical sciences and energy; social sciences, and computer and information sciences.

If you are new to the Research Foundation, or would just like to learn more, review the Intro to Sponsored Programs course.
**Roles and Responsibilities**

The RF is the legal recipient of the award on behalf of the campus. You are accountable for the proper fiscal management and conduct of the project.

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
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<tr>
<td>Principal Investigator</td>
<td>When you function as a funded researcher, you assume fiscal and legal responsibilities. Each Principal Investigator is responsible for assuring that the terms of the award are met and the policies of the campus are followed.</td>
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<td>You must keep in mind that sponsoring agencies, your campus and your academic department are all stakeholders in your success and each may have specific requirements they wish fulfilled.</td>
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<td>Generally a PI must:</td>
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<td>1. Conduct and manage the technical research</td>
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<td>2. Comply with all applicable state and university policies, procedures, and laws</td>
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<td>3. Comply with all terms and conditions of the sponsored award</td>
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<td>4. Manage project funds efficiently and effectively within approved budgets</td>
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<td>5. Ensure that the project is completed in a professional manner</td>
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<td>6. Accept fiscal responsibility on behalf of his/her department, administrative unit, and/or campus in the case the project is over extended or an unauthorized expenditure is disallowed by the auditors*</td>
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<td>*In such cases the academic unit must cover the cost</td>
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<tr>
<td>Role</td>
<td>Responsibilities</td>
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<td>------------------------------------------</td>
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<tr>
<td>Campus Sponsored Programs office</td>
<td>All SUNY campuses have a dedicated staff that assists in the development and submission of new grant proposals.</td>
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<td></td>
<td>The primary mission of each Research and/or Sponsored Programs office (SP)* is to promote extramural funding of research and scholarly activity and to help you, either individually or as part of a group, by</td>
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<td></td>
<td>▪ Providing administrative services to help meet the requirements of the sponsor, Research Foundation and the campus</td>
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<td>▪ Ensuring you are protected from any undue harm prior to the acceptance of a sponsored program</td>
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<td>▪ Verifying that the project does not</td>
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<td>o Challenge institutional integrity</td>
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<td>o Threaten your academic freedom, or</td>
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<td>o Overburden you with management procedures</td>
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<td>▪ Protecting the campus from additional conflicts by making certain no unnecessary risks and liabilities are undertaken</td>
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<td>▪ Ensuring proper stewardship of sponsored funds</td>
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<td>▪ Creating mechanisms for accountability</td>
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<td>▪ Developing procedures for the proper use of sponsored funds</td>
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<td>▪ Interpreting sponsor’s rules</td>
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<td>▪ Establishing compliance with public policies</td>
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<td>▪ Filing assurances and certifications regarding regulatory compliance, and</td>
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<tr>
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<td>▪ Serving as the official liaison between the campus, the Research Foundation and the funding agency</td>
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<td>* Office names vary by campus</td>
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<tr>
<td>Research Foundation</td>
<td>The Research Foundation is the legal recipient of the awards administered by them.</td>
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<td></td>
<td>The RF assists campuses and faculty by:</td>
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<td>▪ Review, negotiation, and acceptance of sponsored agreements on behalf of campuses</td>
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<tr>
<td></td>
<td>▪ Management of central accounting functions including billing and fiscal reporting to sponsors</td>
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<td>▪ Compliance assistance</td>
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**Additional Involved Parties**

In addition to your responsibilities, the below parties are or may be involved in your project.

**Operations Manager (OM) and/or Deputy Operations Manager:**
Reporting to The Research Foundation President (RF), the Research Foundation Operations Manager (OM) serves as the top level Research Foundation executive on campus and is responsible for supporting SUNY’s research mission and the successful implementation of the RF’s strategic plan. The campus president nominates an individual from the campus to be considered for the OM role. The OM is responsible for all Research Foundation operations on campus, including:

- sponsored program administration services to the SUNY community (faculty, students, and staff) and stewardship to our sponsors
- creating an environment to support and increase sponsored program funding
- creating an environment to increase technology transfer and commercialization in support of SUNY’s efforts to revitalize New York’s economy.

**Co-Principal Investigator/Project Director:**
Other person(s) primarily responsible for the scientific, technical, and administrative conduct of a project. In this secondary role to the PI, a Co-PI:

- Provides leadership over a specific task of the project
- Coordinates with his/her Research Foundation, if at another institution
- Coordinates necessary approvals, if at other institution
- Contributes to managing the project and any reporting requirements

The appointment of Co-Principal Investigators does not supplant the need for one individual to be designated as “corresponding” investigator.

**Collaborator:**
A person or entity typically *volunteering* some effort to conduct one minor task, measurement, or analysis. He or she is not compensated and is not involved in management or reporting if a project is funded. He or she may be asked by a sponsor for a letter explaining contribution to the project.

**Sponsor:**
A sponsor is a person or entity who funds the sponsored program. There are three main types of sponsors.
- Federal agencies
- Other government agencies (state or local government)
- Private entities such as foundations, corporations or individuals
Starting Out: Proposals and Funding

Overview
You have primary responsibility for obtaining and managing awarded funds, from finding funding sources to closing out the award when research is complete or the funding ends.

Your Research/Sponsored Programs office can assist you in all aspects of any phase during the grant process.

Developing a Concept
A good proposal stems from a good concept. Your work should link to an important problem, challenge, or new idea.

What is a “good” idea?
For research, a good idea is one which adds to the general knowledge base, brings a new perspective or fills holes to previously conducted research. For other types of projects, the good idea may fill a need for the institution or the community at large. A thorough literature review will be essential to provide the background and rationale for your work.

Figure 3.1: The Grant Process
Preparing a strong proposal requires a significant investment of time, ingenuity, and energy. The sections below will help you focus your efforts on specific principles helping you accomplish this goal. A host of factors impact the probability of success. It is best to use each suggestion as a guideline and not as a hard and fast rule. Knowing how to draft a good proposal and having the time to do it may be two separate things. Be sure you have a sound plan prior to putting the application together; this will help make certain you do not run out of time or get discouraged and rushed in the proposal preparation process.

“A good proposal is a good idea, well expressed, with a clear indication of the methods for pursuing the idea, evaluating the findings, and making them known to all who need to know.”

- National Science Foundation

Proposals should be concise if responding to a solicitation. Contact the program officer at the sponsoring agency for details as you develop your concept and subsequent proposal. Also consider getting input from peers prior to discussing new lines of research you have developed. If your proposal is petitioning for unsolicited funding, you still need to meet some basic guidelines; your idea’s impact on your industry or the community as a whole, expertise available and needed, the cost effectiveness of your plan, and how you will evaluate and disseminate findings.*

* This is not an all inclusive list. Refer to standard proposal guidelines from potential sponsors or grant writing resources for specific instructions.

Check out some useful resources to help you prepare a proposal

- In the Information for Researchers and Administrators section of the RF Home page, click on Sponsored Program & Business Development Funding. (Scroll to the bottom for some self-paced resources)
- Check with SUNY Center for Professional Development on the next session of the Grants and Proposals: If You Write It, They Will Fund, a virtual (SUNY) instructor-led course.
**Clearly Identify Your Idea**

Having a clear and concise plan of how to carry out your project will help you scale your project. Each potential funder will want to know how far along your project is in development, what your intended goals and objectives are (both short and long term), why the idea is important or revolutionary, how much will the project cost (not just in the short term), and how long might it take until progress is made. Knowing, or at least attempting to answer, a majority of these questions will help you bring attention to your project’s potential. Creating enthusiasm for your idea helps get funders behind your work. Also, being aware of the current stage of your idea will determine which solicitations are best to pursue. So, this exercise is important to undertake prior to beginning to respond to a solicitation in earnest.

**Looking for Funding**

The best and most logical first step is locating funding for your idea(s). You probably already have a good idea, from past experience or working with mentors, of agencies and foundations typically providing support for your area of interest. Below are the common resources for finding funding.

**View Common Sites**

Funding options are listed on the RF web site. In the Information for Researchers and Administrators section of the RF Home page, click on Sponsored Program & Business Development Funding.

- **Public Funding** sources such as Federal and State Government agencies (e.g., www.grants.gov or www.NYSTAR.state.ny.us)
- **Private Funding** sources, many noted in the Foundation Center database (www.foundationcenter.org)

Searchable databases provide many options to focus on your area of interest. One example, to which the RF and SUNY subscribe, is the Community of Science Pivot database.

<table>
<thead>
<tr>
<th>COS Pivot Database – The RF/SUNY suggested site</th>
</tr>
</thead>
<tbody>
<tr>
<td>This database combines funding opportunities and professional profile components. The funding database is a comprehensive listing of opportunities from federal, state, and private sponsors both national and international.</td>
</tr>
<tr>
<td>✷ Identify specific keywords associated with your research interests.</td>
</tr>
<tr>
<td>✷ Set up email notifications for new opportunities that meet your search criteria.</td>
</tr>
</tbody>
</table>

While the COS Pivot database does provide information on some private foundations, there are more comprehensive databases strictly targeting these opportunities. A free resource is [Guidestar](http://guidestar.org).
More detailed and user friendly databases are available from The Foundation Center and Metasoft, however these sites require paid subscriptions. Consult with your Sponsored Programs or Development office to determine if the campus has a subscription to one of these databases.

**Locate Fresh Leads**

Even if this is the case, you have opportunities to locate some fresh leads starting with the resources on the Connect, Collaborate, and Find Funding webpage:

- **Mentors/Peers** – who in your field has had success? Are they willing to speak with you about your project? This is probably the most underutilized resource available. Advisors and former co-workers (post-docs and fellow graduate students, etc.) can also serve as a good place to start to identify previously untapped resources.

- Leverage the capacity of the SUNY research community and support SUNY and the Entrepreneurial Century with Find a SUNY Scholar, a database of more than 21,000 profiles of SUNY faculty experts.

- Access the SUNY Distinguished Academy to connect with faculty having achieved the highest level of academic excellence, a rank that can only be designated by the Board of Trustees.

- **Professional Journals** – all publications stemming from funded research must provide a notation of who supported the work. If you see a project that is similar in nature to yours it may be beneficial to make contact with that funder, or at least review the programs they offer for support on a regular basis.

- **Professional Conferences** – much like professional journals, conferences offer detailed information about sponsors in your area of study. Take note of each and do a little research on funding opportunities that may help you succeed in your search. Look for sponsor officials who may be attending the conference.

**Identify a Good Solicitation**

Once you identify a potential solicitation it is prudent to begin assessing the likelihood of your chances for that specific solicitation; this will help you select only the best candidates for funding your projects. The best way to do this is to get to know the sponsor.

- Know the sponsors priorities: find out which specific areas they are funding and match them with your own research priorities.

- Know what types of proposals have been previously funded: look at their annual report to see who they have been funding, and if the awarded grants were for programs similar to yours.

- Contact the sponsor: studies have shown that the best thing a PI can do to increase their chances of getting funded is to contact the program officer. Program officers can provide up to date information about available funds, discuss your project with you and how it would or wouldn’t fit into their program, and possibly even read a summary or draft of your proposal.
Read the sponsor’s guidelines and procedures: This is where you should call upon the resources of your Sponsored Programs office. Typically they can give you some insight about a specific solicitation. You may also want to ask if other investigators at your institution have been successful.

**Award Types**

Consider the type of award agreement you are considering entering into with a sponsor. Types of awards include:

**A GRANT** is defined as an award mechanism to transfer money, goods, property, services or other items of value to universities in order to accomplish a public purpose. In general, the following characteristics describe a grant:

- No substantial involvement is anticipated between sponsor and recipient during performance of activity.
- The award comes with terms, conditions, and/or other contractual requirements that need to be met.
- There are budgetary restrictions that must be followed.
- Reports may be required including financial reports and technical or progress reports.
- Documentation of expenditures.
- Deliverables of any kind, including the sharing of research results.
- There is a start and stop date.

**A CONTRACT** is defined as a binding agreement between parties for the purpose of securing goods or services. In general, the following characteristics describe a contract:

- There is extensive input from the sponsor into the tasks to be performed.
- The award mechanism used by the sponsor is a contract.
- Principal purpose is for direct benefit or use by the sponsor.
- The sponsor requires formal reports of any kind, including financial or technical.
- Invoicing or billing is required.

The contracting mechanism also has terms and conditions such as:

- Ownership of intellectual property.
- Right of first refusal, or right of first negotiation of intellectual property.
- Ownership or access to research results.
- Publication review of faculty, graduate student or post doc research.
- Deliverables of any kind.
- There is a start and stop date.

**A GIFT** is defined as any item of value given by a donor who expects nothing of significant value in return, other than recognition and disposition of the gift in accordance with the donor's wishes. In general, the following characteristics describe a gift:
No contractual requirements are imposed and there are no "deliverables" to the donor. However, the gift may be accompanied by an agreement that restricts the use of the funds to a particular purpose.

A gift is irrevocable. While the gift may be intended for use within a certain timeframe, there is no specified period of performance or start and stop dates.

There is no formal fiscal accountability to the donor.

A SUBCONTRACT is an agreement between your institution and another where you are not the primary award recipient. Typically, in these agreements, you are performing a piece of a larger project which was awarded to the other institution. A subcontract specifies the terms between the two institutions and outlines what you are expected to do as well as provides the budget for your work.

Other types of agreements are Cooperative Agreement, Clinical Trial, Vendor, Data Use, Material Transfer, or Consulting agreements. All of these agreement types are typically funded as contracts.

Award types are managed, reported and monitored in different ways. Once a funding opportunity has been identified, contact your Sponsored Programs office. They can guide you through the rest of the proposal development process.
Developing Proposals

Overview

There are important standard components in a good proposal; omission of any of these components jeopardizes your chances of getting funded.

No one wants to have their application ‘rejected without review’ for a technicality. Reviewing and preparing your application according to these instructions will guarantee that your application is reviewed. In turn, each application announcement draws a very high number of responses.

![Fig 4.1 Application Statistics from 2011](image)

Application Guidelines

All solicitations post specific guidelines on how applications must be prepared for sponsor review. Start with a logical outline. Develop an outline that either follows the specifics or one that leads the reviewer from significance to specifics of proposed activity.

Some proposal guidelines prescribe sections; if so, **DO NOT** deviate from them. It is imperative that you follow the instructions each sponsor posts. These instructions outline the very specific ways in which an application must be developed.

The next figure identifies the general components of both a research and a humanities or training grant proposal.
**Key Components**

Take special note of the sections given below. These are components that should be thoroughly reviewed with your Sponsored Programs office to reduce any errors or surprises later in the process if your project is funded.

**Budgeting**

Developing a budget can seem like an intimidating and daunting task; it needn't be. Your Sponsored Programs administrator is well versed in how to draft a budget. The administrator will know how to calculate some of the costs, what can and cannot be included, and help ensure that you haven't forgotten any potential costs. A proposal budget typically consists of two parts: the *budget form* and the *budget justification*, where you provide an explanation for how you arrived at the figures given on the form.

Some basic tenets are:

- All costs need to be **reasonable**. You must make sure your costs reasonably reflect what is needed to complete your project.
All costs must be allowable. There are some rules regarding what are allowable costs. Talk with your Sponsored Programs administrator to identify those rules.

All costs must be allocable. This means that the costs must be used to solely advance the work of this sponsored project, if awarded.

Good budget development ensures you have the financial resources to complete your project as proposed and, if awarded, limits the potential for difficulties in post-award fiscal management. To help you begin the development of your budget, below is a list of the more common budget items and some guidance for each.

### Personnel Costs

The RF is legally obligated to properly classify workers based on the criteria listed below. You are obligated to ensure that personnel budgeted in an application are properly classified.

A project may incur significant delays if an error is made in the application budget and then must be changed during the post-award phase of the project. To avoid these unnecessary delays budget employees and consultants using the following guidelines:

#### Employee versus Consultant

In general an employee is someone whose primary employment is as a New York State or Research Foundation of SUNY employee.

A consultant does not have a state or Research Foundation appointment and will provide specific and measurable outcomes to a specific task in a separate scope of work. Examples include delivery of a training curriculum, review and opinion of experiment results, or establishment of a clinical trial protocol on behalf of a clinical research organization. Typically, a consultant is not a New York State or Research Foundation of SUNY employee.

#### Institutional Base Salary

The actual base salary of the individual who will work on the project. Do not guess at this figure, your Sponsored Programs office will be able to access this information and provide you with the most up-to-date and accurate figure. In your justification be sure to explain, in some detail, why the individual was chosen for the work.

#### Fringe Benefits

A benefits package for being employed by the institution. Most employees of a project will receive fringe benefits. Carefully consider the time frame of the project. This will allow you to determine which fringe benefit rate to use. Do not undersell this value.

*When an award is made, the fringe benefit rates in place at the time the expenditure occurs will be assessed. So regardless of how you initially budget a project, the current rate will apply, so it is in your best interest to use the projected fringe rates.*

The cost of personnel to conduct a project is typically the largest and most important component of any budget.
## Equipment

The federal definition for equipment is something with a useful life of one year or more and with a unit cost of $5,000 or more. Some sponsors will have different criteria for equipment which you will need to use. Items with a lower cost, including computers, should be included in the materials and supplies budget line.

## Tuition Remission

If you are including a student research assistant as part of your research team, you can budget for tuition remission.

## Subrecipient (Subaward) versus Independent Contractor (Supplier)

Budgeting a sub-awardee versus an independent contractor is similar to the dilemma posed by budgeting an employee versus a consultant. What to consider in this situation only differs in that:

- A sub-awardee is an academic institution or other outside entity providing significant intellectual contributions to the proposed project. It is anticipated that a subrecipient will provide results of an entirely separate project team who will be working on a separate research question or other component that will add significant intellectual value to your overall project.

- An independent contractor is a service provider that will perform a task which does not require any “new” intellectual contributions to complete the work. Keep in mind that any work contracted to an independent contract will be fully owned by the Research Foundation, and the contractor will have no rights to the work performed.

Do not use this arrangement to avoid indirect costs of subcontractors. The terms of an independent contractor arrangement will not be attractive to potential collaborators.

See [Appendix: Subawards versus Supplier](#) for decision making assistance.

## Materials and Supplies

Materials and Supplies are the costs you need to perform the experiments or field work of the project. When developing your budget it is best to also develop a detailed justification to complement the amounts you are requesting. Succinct descriptions of not only the cost but what is necessary will ultimately make your efforts successful.

All sponsors want to know that the funds will ultimately be spent. Give them a reason to choose your project over another team. Time and again reviewers highlight a lack of detail about a budget to know if the costs are efficient and an effective use of money.
**Travel Expenses**

Conference and research travel are common aspects of many sponsored awards. The RF cannot reimburse above the Federal per diem rates unless there is acceptable written justification showing how the award benefits from this additional cost. For example, if a conference is being hosted at a hotel and there is a published, negotiated conference rate (higher than the per diem), the RF can reimburse at the conference rate with documentation.

<table>
<thead>
<tr>
<th>Conferences</th>
<th>If you need to travel internationally, check with your Sponsored Programs officer before making any travel arrangements. There could be restrictions on foreign travel based on sponsor policy or other Federal regulations, including export controls.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flight Information</td>
<td>Flight reservations can be made either directly with the airline, through a website, or through a University-approved travel agent. Utilizing these agents will enable the expense to be directly billed to the RF and will eliminate the need to charge a personal credit card and wait for reimbursement.</td>
</tr>
</tbody>
</table>
| Travel Reimbursements | All requests for travel reimbursement require original detailed receipts.  

- Conference travel requires proof that the traveler actually attended the conference. Acceptable proof is a copy of your conference name tag or a copy of the conference brochure.  
- Travel for meetings requires a copy of the written agenda. |

**Subject Costs (Human or Animal)**

Sometimes awards provide payments to human subjects as an incentive for them to participate in the study. If you intend to supply gift cards, cash, or other non-cash incentives be sure to discuss, with your Sponsored Programs officer, how to handle these payments shortly after your project account is established.
**Direct vs. Indirect Costs**

The Indirect Cost, referred to as Facilities and Administrative (F&A) cost, is comprised of negotiated costs an institution contributes to a project, and is thus reimbursed for those expenses. Costs include everything from lighting, administrative personnel expenses, computer networks, telephone services, etc.

Because the sponsor is providing F&A costs directly to the institution it is not acceptable to charge costs that cannot be allocated to a specific cost in a project.

<table>
<thead>
<tr>
<th>Direct Costs</th>
<th>Can be identified specifically with a sponsored project, instructional activity, or other sponsored activity, and thus directly assigned relatively easily with a high degree of accuracy. Examples: Salaries and wages, Fringe benefits, Equipment, Supplies, Utilities, Travel or Publication expenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirect Costs</td>
<td>Referred to as facilities and administrative (F&amp;A) costs by the federal government; sometimes referred to as “overhead.” Defined as expenses that cannot be directly and uniquely assigned to any particular project and aligned with two categories; <em>Facilities and Administrative</em></td>
</tr>
</tbody>
</table>

To help you better determine whether a cost is a direct expense vs. indirect cost you must consider first the impact the cost actually has on a project. For example, if a computer is being purchased by a grant, the federal sponsors require the institution have documentation that the computer will only be used to further the goals of the project. If for some reason the cost cannot be reasonably allocated directly to one grant and no other activity, the question will arise - Why is the grant being used to purchase the computer?

It is important that you consult your Sponsored Programs office about any cost you include as a direct charge. The staff will help you determine how to best proceed in what should be and should not be a direct cost for your project.

Indirect costs are calculated as a percentage of your direct costs. You need to contact your Sponsored Programs office to find out the percentage to use and the direct cost base your campus has negotiated.

Other budget considerations include project evaluation, participant support costs, insurance, project specific audit costs, and more. Again, work with your Sponsored Programs office to project your budget.

**Budget Justification**

Your project will be a success when you have the resources to adequately cover your costs. As we all are aware, federal, state, and even private funders are taking issue with rising research costs. Keep this fact in mind when constructing your project budget and justification. In your budget justification you want to show, in as much detail as possible, why certain costs are necessary to conduct the project. Providing a good rationale on certain items can help you provide more transparency to the application reviewers.
Compliance

Most research involves compliance with some federal laws and regulations governing the conduct of the work. Below is a list of the more common regulatory areas affecting federally funded research projects.

This is not an all-inclusive list so your work may involve laws and regulations that are not mentioned here. If there are any questions or concerns about any regulatory issues you should contact your Sponsored Programs office.

<table>
<thead>
<tr>
<th>Human Subjects Protections</th>
<th>All human subjects research, federally funded or not, must be reviewed by your campus’s Institutional Review Board (IRB). Many proposal applications will ask if the research proposed involves human subjects and, if so, request the IRB approval date. Be sure to know well in advance the IRB protocol review schedule so that you can be sure to have a complete review prior to the proposal deadline.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Protections</td>
<td>All research involving animals, federally funded or not, must be reviewed by the campus Institutional Animal Care and Use Committee (IACUC). Many proposal applications will ask if the research proposed involves animals and, if so, request the IACUC approval date. Be sure to know well in advance the IACUC protocol review schedule so that you can be sure to have a complete review prior to the proposal deadline.</td>
</tr>
<tr>
<td>Conflict of Interest</td>
<td>To ensure the validity of your research it is imperative that there be no personal financial conflict of interest, real or apparent. Be familiar with your institution’s conflict of interest policy. Also be aware of your prospective sponsor’s conflict of interest requirements. Some sponsors, particularly those in the Public Health Service, have stringent requirements of which you need be aware.</td>
</tr>
<tr>
<td>HIPAA</td>
<td>The Health Insurance Portability and Accountability Act (HIPAA) limits the use of protected health information that is held or transmitted in any form or media whether electronic, written, or oral to protect the privacy of patient health information. If your research involves the use of individual medical records you need to be familiar with the HIPAA guidelines.</td>
</tr>
</tbody>
</table>
| Export Controls | These federal regulations involve the disclosure, shipment, transfer or transmission of any commodity, technology or software that is on the Commerce Controlled List, Munitions List, or the Office of Foreign Assets Control Embargoed List for use outside of the U.S.

Prior to taking any piece of research equipment out of the U.S or sharing it domestically with a foreign national. You need to determine if it falls under any of these lists. If so, you will need to get a license prior to leaving the country.

Since obtaining a license can be very time consuming, you will need to check in with your Sponsored Programs office early to determine if a license is needed. |
|---|---|
| Confidential/Research Data | Proprietary Data should be disclosed and marked as confidential as part of the application.

Disclosure of information prior to taking the appropriate protections could limit our ability to commercialize research results.

Please consult your Sponsored Programs officers during the application for consistency. |
| Research Misconduct | Fabrication, falsification or plagiarism in proposing, performing and reviewing research or in reporting research results constitutes research misconduct.

Your campus has a policy and procedure for handling research misconduct. You should become familiar with both in the event that you are a witness to such conduct. |
| Use of Hazardous Material, Blood-Borne Pathogens | Campuses conducting research where these materials are used have committees that ensure that they are used appropriately and will not pose a hazard to the research subject, researchers, or the community at large. |

**Compliance Training Resources**

The RF provides resources to you and your project staff to learn about regulations and compliance standards. Your course completion is tracked, giving verifiable proof to sponsors of your knowledge of the subject areas.

**CITI Training:** A system-wide license for all campuses to utilize specialized training on a number of research-related topics including Responsible Conduct of Research, Financial Conflict of Interest, and Humans Subjects and Animal Care.

**WeComply:** A system-wide license for all RF-affiliated campuses to access general business compliance training including Sexual Harassment Prevention, Financial Conflict of Interest, Workplace Violence, Business Etiquette and more.

Contact your Sponsored Programs office if you need assistance accessing these tools.
Submitting Proposals

Overview

Representatives in your OSP office are designated by the Research Foundation as the primary signatory on all applications submitted on behalf of SUNY Campuses; your campus will review prior to the submission of an application.

Provide a full copy of your application at least a few business days prior to a submission deadline. It is always helpful, if possible, to give your OSP office a few days’ notice before sending the application for review.

An institutional document of compliance. Although this document goes by a myriad of names and formats, you must follow the format and get the appropriate signatures that are required by your campus Sponsored Programs office. This document is the lone item that gives your OSP office the final approval to submit your application.

This document requires you, as the PI, to identify the basic elements of your application. (Examples: What is the title? Do you have animal or human subjects? Who will be the sponsor for your proposed work? Do you have additional PIs or Co-PIs.)

These internal documents are vitally important in ensuring compliance with federal and campus policies. Be sure to get this document done early in your application process, as it is relatively simple to complete and easy to get out of the way early.

Additional Institutional Requirements. Each SUNY campus may require additional components to be included with your application prior to review. Contact your Sponsored Programs office for specific campus requirements.

Reviewing the guidelines for additional criteria is a normal component of review prior to an application being submitted. Getting an idea of what is missing early, and identifying who will assist you is crucial to your success.

Award Acceptance and Negotiation

The Research Foundation negotiates and accepts all awards on behalf of the PI and the campus. The Research Foundation representatives have the knowledge and expertise to ensure that faculty, staff, and students are not adversely affected by the agreement terms.

The agreement terms specify the amount of the award, the start and end dates of the grant, any reporting requirements, and deliverables expected at the end of the grant period, and will outline any other requirements the sponsor may have.
Overview

Congratulations on receiving your award! The intent of this section is to provide guidance on the financial and other post-award administration of your project. Keep in mind that the material discussed below is not intended to be a comprehensive review of all issues that may arise. You should contact your Sponsored Programs office whenever you have concerns or questions.

![Lifecycle of a Grant](image)

Figure 6.1 Lifecycle of a Grant

Revisiting the grant lifecycle above, there are processes assigned to you, the PI, and the RF either through the RF central office or by representation of your campus Sponsored Programs office. Your campus Sponsored Programs office is there to assist you in keeping on track with your research and sponsor requirements. In the end, remember, you are still accountable for all requirements.

Award Establishment

The Research Foundation will create a project specific account, after your official award notice has been accepted, referred to as PTAE0 (pat-ay-oh). The account number consists of an award number, a project number and a task number.
This specific account is created to track all project expenditures. You will be notified when the account is established.

Prior to any account establishment, the Sponsored Programs office verifies all appropriate compliance approvals are complete.

**Monitoring Sponsored Award Financial Activity**

The RF offers multiple web-based tools within the RF Report Center to allow you to monitor the financial activity of your sponsored award(s). Both the **PI Dashboard** and the **RF Activities Interface Reporting tool (RF AIR)** provide you with (or others whom you designate) the ability to see the award’s budget, what has been spent, what is encumbered, and what balance remains in each budget category. In order to access these systems, contact your campus sponsored programs office for assistance.

You are responsible for verifying payment of all expenses submitted and ensuring there are no unauthorized charges against the award. For this reason, we recommend that you (or your designee) reconcile the activity of the account on a *monthly* basis.

**Awarded Budget Revisions**

As you are aware, your award has a budget that has been approved by the sponsor. Part of effectively managing any award is to stay within the originally agreed upon budget parameters. The **RF AIR** is an effective tool to help with this.

It is not uncommon to need budget category revisions. In this case, you, as the PI, cannot simply change the budget. This is because each sponsor has specific policies when it comes to making budget modifications, typically outlined in the award, which must be adhered to in the management of a project. If you need to modify your budget you must work with your Sponsored Programs office to make these modifications.
**Key Award Considerations**

Though not an all-inclusive list, the items below are all major concerns while managing your award.

**Project Specific Personnel**

Hiring project staff may be a necessity to complete your work. The Research Foundation complies with applicable laws and regulations that have been established to maintain salary and wage equity and for the consistent treatment of all its employees. As such, some measures will be taken, during both the search and hiring process, to ensure that the final candidate was chosen fairly and has the appropriate credentials.

Before any commitments are made, verbally or in writing, you **must** contact your campus Human Resources Department to ensure you are complying with campus policies on employee hiring.

**Effort Reporting**

Each project budget or award will designate an amount of effort a PI and other project staff will devote to a project. If any changes are expected to your effort you must contact your Sponsored Programs office immediately. Changes to effort generally have a ripple effect through the budget and can significantly affect the terms of your research agreement.

You will be required to certify your effort and the effort of your research staff for all federal and federal flow-through sponsored programs. This is done electronically via the RF’s Effort Certification and Reporting Technology (ectr) two or three times per year, depending on your campus. Certifying effort requires that you, or a person having firsthand knowledge, acknowledge that all personnel provided effort as agreed to in the project proposal. Failure to certify employee effort on a timely basis could result in disallowances. Any nonexempt employees participating in a project will certify their effort via their biweekly timesheets.

Contact your Sponsored Programs office for additional information.

**Purchasing**

The Research Foundation must ensure that all expenditures comply with sponsor, RF and campus guidelines. In addition, in accordance with federal requirements all expenditures must be **reasonable, allowable and allocable** to the sponsored project. The roles of purchasing and accounts payable staff are to assist you with the purchase of necessary project items and equipment at the best price possible; establish quality relationships with suppliers that will meet project needs; and get goods, products and services to you as quickly as possible. You will want to ensure funds are available to support the purchases.

**Travel**
Travel plays an important role in many sponsored projects. Some sponsors may have specific travel conditions or restrictions that you must abide by. Principal Investigators are responsible for certifying that all travel undertaken in connection with sponsored projects are made for the express purpose of carrying out the project objectives. Individual travelers are responsible for the appropriate use and accurate accounting for travel funds provided to them, as well as for compliance with sponsor and RF policies. Therefore, prior to leaving on any trip, it is best to consult with Sponsored Programs staff to ensure you have accurate information and necessary approvals.

Cost Transfers

A cost transfer reassigns expenditures previously recorded in one award to another award. The award to which a cost is transferred must benefit from the goods or services related to that charge, and the charge should be allowable under sponsor guidelines.

Expenditures should be charged to the appropriate award when they are incurred. If it is necessary to transfer expenditures to a different award for approved circumstances, the cost transfer should occur within 90 days of when that need is identified.

Prior to initiating a cost transfers you should contact your Sponsored Programs office for guidance.

Reporting

Financial, technical, and progress reports are often required by sponsors on a fixed schedule throughout the lifetime of an award. These reports provide the sponsor with assurance that project activities are moving forward according to the terms of the agreement. Typically, you, as the PI, are responsible for making sure

- All progress reports are submitted to the sponsor on time
- Copies of all reports, along with the transmittal letter or e-mail, have been provided to the Sponsored Programs office

Failure to provide required reports can result in funding delays in multi-year awards, early termination of the award by the sponsor, and can lead to the Research Foundation not being able to apply for any future awards.

The RF is responsible for the submission of any required fiscal reports.

Extending Awards

Sometimes a project cannot be completed in the agreed-upon timeframe. In this case, you may need to request a no-cost extension to allow for time to finish the work. Requests for no-cost extensions

- usually include a justification and a projected budget that provides a spending plan for any unused funds
must be coordinated with your sponsored programs officer
should be done at a minimum of 60 days in advance of the award’s termination date.

**Intellectual Property**

The development of intellectual property is a natural and regular outgrowth of research programs and other scholarly activities being conducted across the SUNY system. Intellectual property includes anything that marketable, such as inventions, books, articles, study guides, syllabi, workbooks or manuals, bibliographies, instructional packages, tests, video or audio recordings, films, slides, transparencies, charts, other graphic materials, photographic or similar visual materials, film strips, multi-media materials, three-dimensional materials, exhibits, and computer software.

To protect your work from illegal copying, these items can be patented, copyright protected, or trademarked.

The SUNY policy on intellectual property states the Research Foundation is the owner of all intellectual property created through the use of SUNY resources or facilities, supported directly or indirectly by funds administered by the Research Foundation, developed within the scope of employment by SUNY employees or agreed in writing to be a specially commissioned work. Exceptions to this ownership right are regular academic work products, work created solely for the purpose of satisfying a course requirement, work covered by a contractual agreement and work resulting from outside consulting activities.

Additionally, it is a requirement on federal grants to disclose intellectual property developed under the grant. You should contact your Sponsored Programs office regarding compliance with this requirement.

Your campus wants to work with you to ensure that your intellectual property is identified and protected. In order to do so, you must disclose your discovery or development as soon as possible. If you are located at a university center or medical university, you should contact the technology transfer office at your campus to discuss and disclose your discovery. If you are located at one of the SUNY colleges, contact your Sponsored Programs office, who will put you in contact with the Research Foundation Technology Transfer Coordinator.

**Closing Awards**

Once the award period officially ends, each sponsor establishes its own deadlines for the submission of final financial and technical reports, as well as final invoices. Please be aware of, and ready to meet these deadlines. Typically the close-out process is smooth, provided that all reports and all expenses have been judiciously accounted for.
Appendix: Policies, Procedures, and Regulations

You are obligated to adhere to any and all policies, procedures and regulations throughout the lifecycle of your award.

Policies and Procedures
Access the RF policies and procedures through the links below:

- RF Policies
- RF Procedures

Campus policies and procedures may vary slightly from, and supersede, RF policies and procedures. Contact your campus Sponsored Programs office for guidance.

OMB Circulars
The U.S. Office of Management and Budget (OMB) Circulars serve as the backbone of all federal contracting and are generally the guidance documents that can be referred to whenever questions arise.

The Research Foundation has an obligation to follow the regulations provided by the federal government outlined by each circular.

- Circular A-21 establishes principles for determining costs applicable to sponsored awards
- Circular A-110 establishes the requirement to consistently and uniformly apply principles
  Therefore, the principles of A-21 are applied to all Research Foundation accounts, regardless of the sponsor or source of funds
- Circular A-133 establishes the basis for audit requirements and standards

To ensure compliance there is an annual A-133 audit. In this audit, the financial systems are reviewed and a final report is offered to identify the Research Foundation’s compliance with A-133’s standards. The report is filed with the federal government, and made available to anyone looking to do business with the Research Foundation.
Appendix: Subawards versus Supplier

A subaward is likely appropriate if you can answer “yes” to any of the following questions:

- Does the entity’s scope of work (SOW) represent an intellectually significant portion of the programmatic effort of the overall project?
- Does the entity have responsibility for programmatic decision making?
- Could the entity’s work result in intellectual property developed or publishable results (including co-authorship)?
- Will the entity need animal and/or human subjects approvals for its portion of the work?

The following information provides tips to distinguish a subaward from the supplier situation.

<table>
<thead>
<tr>
<th>If the situation involves an…</th>
<th>The relationship is a…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entity selling goods or services as part of their routine business operations,</td>
<td>Supplier</td>
</tr>
<tr>
<td>usually at a fixed price or rate (e.g., pipettes, tanks of hydrogen, etc.)</td>
<td></td>
</tr>
<tr>
<td>Entity using human subjects or animal subjects (and needs both the subrecipient’s AND</td>
<td>Subaward</td>
</tr>
<tr>
<td>campus’ IRB or IACUC approval) to do their portion of the work</td>
<td></td>
</tr>
<tr>
<td>Entity conducting a survey using de-identified data, and annual IRB approval is not</td>
<td>Supplier</td>
</tr>
<tr>
<td>required</td>
<td></td>
</tr>
<tr>
<td>Entity who might be a legitimate author or co-author of a paper done on the project</td>
<td>Subaward</td>
</tr>
<tr>
<td>Invention arising from the work done by the subrecipient</td>
<td>Subaward</td>
</tr>
<tr>
<td>Entity performing a test on data we provide to them and whom gives us the results to</td>
<td>Supplier</td>
</tr>
<tr>
<td>analyze</td>
<td></td>
</tr>
<tr>
<td>Entity performing a test on data we provide to them and provides routine professional</td>
<td>Supplier</td>
</tr>
<tr>
<td>services in analyzing the results (e.g., a radiologist reading an X-RAY)</td>
<td></td>
</tr>
<tr>
<td>Entity performing a test on data we provide to them and uses their professional expertise</td>
<td>Subaward</td>
</tr>
<tr>
<td>to contribute to generalized knowledge in new ways</td>
<td></td>
</tr>
</tbody>
</table>
Other procurement actions may be appropriate when the supplier:

- provides the goods and services within its normal business operations
- provides similar goods or services to many different purchasers
- operates in a competitive environment
- provides goods or services that are ancillary to the operation of the RF sponsored project
- is not subject to compliance requirements of the sponsor.
# Appendix: Glossary and Acronyms

## Acronyms

Listed below are common acronyms you may see over the lifecycle of your sponsored program. This is only a portion of the full list. Access the full RF Acronyms and Common Terms list here.

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAAH</td>
<td>American Association for the Advancement of Humanities</td>
</tr>
<tr>
<td>AAALAC</td>
<td>American Association of Animal Laboratory Accreditation Council</td>
</tr>
<tr>
<td>AAAS</td>
<td>American Association for the Advancement of Science</td>
</tr>
<tr>
<td>AACUO</td>
<td>Association for Affiliated College and University Offices</td>
</tr>
<tr>
<td>ACC</td>
<td>Application Control Center</td>
</tr>
<tr>
<td>ACE</td>
<td>American Council on Education</td>
</tr>
<tr>
<td>ACLS</td>
<td>American Council for Learned Societies</td>
</tr>
<tr>
<td>ACO</td>
<td>Administrative Contracting Officer</td>
</tr>
<tr>
<td>ACS</td>
<td>American Cancer Society</td>
</tr>
<tr>
<td>ADAMHA</td>
<td>Administration on Drug Abuse, Mental Health and Alcoholism</td>
</tr>
<tr>
<td>AFDC</td>
<td>Aid to Families with Dependent Children</td>
</tr>
<tr>
<td>AFOSR</td>
<td>Air Force Office of Scientific Research</td>
</tr>
<tr>
<td>AHA</td>
<td>American Heart Association</td>
</tr>
<tr>
<td>AID</td>
<td>Agency for International Development</td>
</tr>
<tr>
<td>AOA</td>
<td>Administration on Aging</td>
</tr>
<tr>
<td>ARI</td>
<td>Army Research Institute</td>
</tr>
<tr>
<td>ARO</td>
<td>Army Research Office</td>
</tr>
<tr>
<td>AUTM</td>
<td>Association of University Technology Managers</td>
</tr>
<tr>
<td>AVA</td>
<td>American Vocational Association</td>
</tr>
<tr>
<td>BAA</td>
<td>Broad Agency Announcement</td>
</tr>
<tr>
<td>BIA</td>
<td>Bureau of Indian Affairs</td>
</tr>
<tr>
<td>BLS</td>
<td>Bureau of Labor Statistics</td>
</tr>
<tr>
<td>CAS</td>
<td>Cost Accounting Standards</td>
</tr>
<tr>
<td>CASB</td>
<td>Cost Accounting Standards Board</td>
</tr>
<tr>
<td>CASE</td>
<td>Council for the Advancement and Support of Education</td>
</tr>
<tr>
<td>CBD</td>
<td>Commerce Business Daily</td>
</tr>
<tr>
<td>CFDA</td>
<td>Catalog of Federal Domestic Assistance</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>CIES</td>
<td>Council for the International Exchange of Scholars</td>
</tr>
<tr>
<td>CPB</td>
<td>Corporation for Public Broadcasting</td>
</tr>
<tr>
<td>CO</td>
<td>Contracting Officer</td>
</tr>
<tr>
<td>COP</td>
<td>Certificate of Proposal</td>
</tr>
<tr>
<td>COS</td>
<td>Community of Science</td>
</tr>
</tbody>
</table>
COGR  Council on Governmental Relations
CURI  College and University Resource Institute
DARPA  Defense Applied Research Projects Agency (formerly ARPA)
DC  Direct Costs
DCA  Division of Cost Allocation (HHS)
DCAA  Defense Contract Audit Agency
DCE  Direct Cost Equivalent
DEA  Drug Enforcement Administration
DEAR  Department of Energy Acquisition Regulations
DFAR  Defense Federal Acquisition Regulations
DHHS  Department of Health and Human Services
DOD  Department of Defense
DOE  Department of Energy
DOEd  Department of Education
DOT  Department of Transportation
EDGAR  Educational Department General Administration Regulations
EDI  Electronic Data Interchange
EFT  Electronic Funds Transfer
EO  Executive Order
EPA  Environmental Protection Agency
ERIC  Education Resources Information Clearinghouse
ERA  Electronic Research Administration
ERS  Economic Research Service
ESEA  Elementary and Secondary Education Act
ETA  Employment and Training Administration
F & A  Facilities and Administrative Costs (formerly Indirect Costs)
FAR  Federal Acquisition Regulations
FDP  Federal Demonstration Partnership
FIE  Federal Information Exchange
FIPSE  Fund for the Improvement of Postsecondary Education
FMC  Federal Management Circular
FOIA  Freedom of Information Act
FR  Federal Register
FSR  Financial Status Report
FY  Fiscal Year
GAO  Government Accounting Office
GEPA  General Education Provisions Act
GPRA  Government Performance and Results Act
GSA  General Services Administration GSL Guaranteed Student Loan
HEA  Higher Education Amendment
HEARS  Higher Education Administrative Resource Service
HED  Higher Education Daily
HENA  Higher Education and National Affairs HHS
      Department of Health and Human Services
IACUC  Institutional Animal Care and Use Committee
IACP  Institutional Animal Care Program
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDC</td>
<td>Indirect Costs (now called Facilities and Administrative Costs)</td>
</tr>
<tr>
<td>IG</td>
<td>Inspector General</td>
</tr>
<tr>
<td>IHE</td>
<td>Institution of Higher Education</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>IREX</td>
<td>International Research and Exchanges Board</td>
</tr>
<tr>
<td>LAR</td>
<td>Laboratory Animal Resources</td>
</tr>
<tr>
<td>MTA</td>
<td>Material Transfer Agreement</td>
</tr>
<tr>
<td>MTDC</td>
<td>Modified Total Direct Costs</td>
</tr>
<tr>
<td>NASA</td>
<td>National Aeronautics and Space Administration</td>
</tr>
<tr>
<td>NCES</td>
<td>National Center for Educational Statistics</td>
</tr>
<tr>
<td>NCURA</td>
<td>National Council of University Research Administrators</td>
</tr>
<tr>
<td>NEA</td>
<td>National Education Association</td>
</tr>
<tr>
<td>NEA</td>
<td>National Endowment for the Arts</td>
</tr>
<tr>
<td>NEH</td>
<td>National Endowment for the Humanities</td>
</tr>
<tr>
<td>NFAH</td>
<td>National Foundation on the Arts and Humanities</td>
</tr>
<tr>
<td>NIA</td>
<td>National Institute on Aging</td>
</tr>
<tr>
<td>NIAAAA</td>
<td>National Institute on Alcohol Abuse and Alcoholism</td>
</tr>
<tr>
<td>NIDA</td>
<td>National Institute on Drug Abuse</td>
</tr>
<tr>
<td>NIE</td>
<td>National Institute on Education</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>NIHR</td>
<td>National Institute for Handicapped Research</td>
</tr>
<tr>
<td>NRA</td>
<td>National Rehabilitation Association</td>
</tr>
<tr>
<td>NRSA</td>
<td>National Research Service Award</td>
</tr>
<tr>
<td>NSF</td>
<td>National Science Foundation</td>
</tr>
<tr>
<td>OFCC</td>
<td>Office of Federal Contract Compliance</td>
</tr>
<tr>
<td>OMB</td>
<td>Office of Management and Budget</td>
</tr>
<tr>
<td>ONR</td>
<td>Office of Naval Research</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>OSI</td>
<td>Office of Science Integrity</td>
</tr>
<tr>
<td>PA</td>
<td>Program Announcement</td>
</tr>
<tr>
<td>PETA</td>
<td>People for the Ethical Treatment of Animals</td>
</tr>
<tr>
<td>PHS</td>
<td>Public Health Service</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>RDA</td>
<td>Recombinant DNA</td>
</tr>
<tr>
<td>RFA</td>
<td>Request for Applications</td>
</tr>
<tr>
<td>RFP</td>
<td>Request for Proposal</td>
</tr>
<tr>
<td>RFQ</td>
<td>Request for Quotation</td>
</tr>
<tr>
<td>SBA</td>
<td>Small Business Administration</td>
</tr>
<tr>
<td>SPA</td>
<td>Sponsored Programs Administration</td>
</tr>
<tr>
<td>SRA</td>
<td>Society of Research Administrators</td>
</tr>
<tr>
<td>TDC</td>
<td>Total Direct Costs</td>
</tr>
<tr>
<td>TGA</td>
<td>The Grant Advisor</td>
</tr>
<tr>
<td>UBIT</td>
<td>Unrelated Business Income Tax</td>
</tr>
<tr>
<td>USC</td>
<td>United States Code</td>
</tr>
<tr>
<td>USDA</td>
<td>United States Department of Agriculture</td>
</tr>
</tbody>
</table>
Appendix: Audits and Site Visits

Sponsors, by virtue of the fact that they are investing money in a sponsored award, are entitled to perform audits of all aspects of the award (financial and programmatic). The following is a list of audit types:

- Pre-award
- Financial statement
- OMB A-133
- Program Specific
- Special Review
- F&A Cost Proposal and Disclosure Statement
- Business System Review (accounting, procurement, property, etc.)

These audits may also be accompanied by site visits where the sponsor sends an individual or team to get a first-hand look at award activity to ensure that it is in compliance with the sponsor’s regulations and the scope of work outlined in the funded proposal.

The RF is obligated to comply with any requests for audits and/or site visits. The RF will provide appropriate personnel and resources to the sponsoring agency to demonstrate compliance.

You must notify the Sponsored Programs office as soon as you are informed of an audit or site visit.