**Orange County Community College**

**Institutional Review Board**

**Policy and Procedures**

July 23, 2013

Contents

[Background 4](#_Toc367439443)

[Oversight of Ethical Principles Regarding Research Involving Humans as Subjects 4](#_Toc367439444)

[Mission 4](#_Toc367439445)

[Basic Principles 4](#_Toc367439446)

[IRB Jurisdiction/Applicability 5](#_Toc367439447)

[Scope of Authority of the IRB 6](#_Toc367439448)

[IRB Policy and Procedures Development 7](#_Toc367439449)

[OPERATIONS OF THE IRB 9](#_Toc367439450)

[Meetings 9](#_Toc367439451)

[Protocol for Full IRB Review Meeting 9](#_Toc367439452)

[Documentation 10](#_Toc367439453)

[Annual Report to VPAA 11](#_Toc367439454)

[Conflict of Interest 11](#_Toc367439455)

[Training and Support to the Campus 11](#_Toc367439456)

[IRB APPLICATION PROCESS 12](#_Toc367439457)

[How to Determine Under What Circumstances to Apply for IRB Approval 12](#_Toc367439458)

[Definition of Research 13](#_Toc367439459)

[Definition of Principal Investigator (PI) and Responsibilities 13](#_Toc367439460)

[Definition of Adverse Event 14](#_Toc367439461)

[Research vs. Classroom Assignment 15](#_Toc367439462)

[Classroom assignments that require IRB review 15](#_Toc367439463)

[Classroom assignments that are exempt from IRB review 15](#_Toc367439464)

[Faculty Responsibility 15](#_Toc367439465)

[Retroactive approval is not granted 16](#_Toc367439466)

[Informed Consent 16](#_Toc367439467)

[When to File a Research Application 16](#_Toc367439468)

[Levels of IRB Review 17](#_Toc367439469)

[Exempt from Full IRB Review 17](#_Toc367439470)

[Expedited IRB Review 18](#_Toc367439471)

[Full IRB Review 20](#_Toc367439472)

[Guidelines for Application Submission 21](#_Toc367439473)

[Procedures of the IRB for Application Review 22](#_Toc367439474)

[Actions of the IRB 23](#_Toc367439475)

[Responsibility of Investigators upon Research Approval 24](#_Toc367439476)

[Appeals 24](#_Toc367439477)

[Periodic Review 25](#_Toc367439478)

[Extension of Research 25](#_Toc367439479)

[Criteria for Periodic Review and Extension of Research by IRB 25](#_Toc367439480)

[Criteria for Review of Adverse Events by IRB 25](#_Toc367439481)

[Failure to Submit Project for IRB Review 26](#_Toc367439482)

# Background

On March 14, 2011, the Board of Trustees approved *Board Policy 5.10, Use of Human Participants in Research*, which reads as follows:

*The College encourages and supports faculty members to develop and conduct scholarly research. The College is also committed to protecting the rights and privacy of all who participate as subjects in research conducted under the auspices of the College and to ensuring that such subjects are aware of the rights and protections available to them. For these reasons, the President shall establish an Institutional Review Board (IRB) for ethical and regulatory oversight of all proposed research at the College which could involve the use of human subjects. Any faculty member who desires to conduct research, or will assign classroom projects to be completed by students involving human subjects must obtain prior approval by the College’s IRB and the Vice President for Academic Affairs before research may begin and before any grants to support such research may be submitted. All such research shall be guided by the College’s mission, vision and values.*

# Oversight of Ethical Principles Regarding Research Involving Humans as Subjects

The Orange County Community College Institutional Review Board is registered with the federal Office for Human Research Protections (OHRP) as Institutional Review Board (*IRB #* 00008790 - Orange County Community College IRB #1). This committee is hereinafter referred to as “the IRB.”

# Mission

The mission of SUNY Orange’s IRB is to protect the welfare of human subject participants by compliance with the federal regulations governing the protection of human subjects, and facilitating the research efforts of faculty, staff, employees and students.

# Basic Principles

SUNY Orange, which includes faculty, staff, employees, and students, is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (referred to as “The Belmont Report”) regardless whether the research is subject to Federal Regulation or with whom conducted, or the source of support or sponsorship.

The three essential requirements relevant to the protection of human subjects in biomedical and behavioral research as set forth in The Belmont Report are:

* Respect for Persons: Involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy;
* Beneficence: Entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm; and
* Justice: Requires that the benefits and burdens of research be distributed fairly.

The principle of Respect for Persons underlies the need to obtain informed consent; the principle of Beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of Justice requires that subjects be fairly selected.

# IRB Jurisdiction/Applicability

1. The IRB is a committee established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.
2. The IRB has the authority to approve, require modifications to, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and SUNY Orange policy.
3. All research or clinical investigations involving human subjects regardless of funding source or sponsorship must be reviewed and approved by the IRB. No intervention, investigation, or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol.
4. Specific determinations as to the definition of “research”, “clinical investigation”, or “human subject” and their implications for the jurisdiction of the IRB under SUNY Orange policy are made by the IRB.
5. SUNY Orange’s Assurance, defined in the next section of this document, with the federal government specifies that all research activities involving human subjects, and all other activities which even in part involve such research, regardless of funding source or sponsorship, must be reviewed by the IRB if one or more of the following apply:
   1. the research is sponsored by SUNY Orange, or
   2. the research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the College in connection with his or her institutional responsibilities, or
   3. the research is conducted by or under the direction of any employee, faculty, staff, or agent of the College using any property or facility of this institution, or
   4. the research involves the use of the College’s non-public information to identify or contact human research subjects or prospective subjects.

# Scope of Authority of the IRB

1. SUNY Orange holds a federal Assurance of Protection for Human Subjects (Department of Health and Human Services), Number 00019384, approved on October 3, 2012, in which it agrees to uphold the ethical principles of The Belmont Report and to apply the Code of Federal Regulations (45 CFR Part 46) to all research involving human subjects regardless of sponsorship or support.

2. It is not the role of the IRB to evaluate or provide rulings on the methodological approach of the proposed research study, the merits of the research design, or the potential contribution of the research to the scholarly literature. *It is, however, the responsibility of the IRB to evaluate each project in terms of the ethical standards with regard to issues such as informed consent, confidentiality, and any risk to the participants.*

3. The Vice President for Academic Affairs or Designee is responsible for exercising appropriate administrative oversight to ensure that SUNY Orange policies and procedures designed for protecting the rights and welfare of human subjects are effectively applied in compliance with its federal wide Assurance with the Office for Human Research Protections (“OHRP”), Department of Health and Human Services.

4. The IRB has approval authority of human subject protocols and can disapprove, modify or approve studies based upon consideration of any issue it deems relevant to human subject protection.

5. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Vice President of Academic Affairs (VPAA) or designee. However, the VPAA or designee may not approve the non-exempt research if it has not been approved by the IRB.

6. The IRB has authority to require progress reports from the investigators and oversee the implementation of the study.

7. The IRB has authority to suspend or terminate a study, or to place restrictions on a study, when it is deemed to be in the best interests of the subjects in that study.

8. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol.

9. The IRB has the authority to access and to make copies of records related to any research approved by the IRB, regardless of the location of those records, for any reason. Where feasible, notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption to on-going research.

# IRB Policy and Procedures Development

1. Pursuant to 45 CFR 46.103, an Institution must assure that it has adequate written procedures in place to support compliance with the federal regulations governing research involving human subjects.
2. Any written procedures shall be approved by the IRB and be presented to the Vice President for Academic Affairs for review and final adoption.
3. The Vice President for Academic Affairs or designated members of the IRB or legal counsel to the IRB shall perform periodic review of the written procedures and recommend to the IRB any revisions or additions to the IRB procedures, consistent with federal regulations, guidelines, or rules and procedures governing SUNY Orange. Any such revisions approved by the IRB shall be presented to the Vice President for Academic Affairs for final adoption.
4. Minor revisions to any IRB forms, checklists, guides or web pages may be performed by IRB office staff as needed, subject to the approval of VPAA or IRB chairperson. Any major revisions shall be presented to the IRB for review and approval.

**Membership of IRB**

1. The IRB is administratively responsible for reporting to the Vice President of Academic Affairs.
2. The Chair of the IRB will be appointed by the Vice President of Academic Affairs. The Vice President for Academic Affairs is authorized to remove an IRB Chair for cause only.
3. The Chair of the IRB appoints the Vice Chair of the IRB with the concurrence of the IRB. The Vice Chair presides over all convened IRB meetings in the absence of the Chair, and has authority to sign all IRB action items in the absence of the Chair. The Vice Chair must be a voting member of the IRB.
4. The IRB shall include at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area, and one member who is not affiliated with SUNY Orange (i.e. not a family member or spouse of an employee, and not an alumnus).
5. The IRB is required to have a minimum of five members, each with varying backgrounds and expertise to provide complete and thorough review of research activities commonly conducted by the Institution (SUNY Orange).
6. All appointments to the IRB are made by the Vice President of Academic Affairs or Designee for tenure of three (3) years. All appointments to the IRB will be communicated by the Chairperson of the IRB and as required, reported to the OHRP.
7. Alternates and non-voting members are also appointed. Alternates will have authority to vote at IRB meetings only in instances where a voting member is unable to attend. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting.
8. The composition of members on the IRB will reflect the diversity of the campus and bring expertise that will assure adequate review of the research brought before the IRB. The IRB membership must be qualified through the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes.
9. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond, or in addition to that available on the IRB. These individuals may not vote with the IRB.
10. Membership may be terminated by notice of the committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapacity to serve the committee adequately. Tenure on the IRB may cover multiple terms by mutual agreement between the member, Chair and Vice President for Academic Affairs.
11. Members and alternates of the IRB are required to complete the National Institutes of Health (NIH) Training course ***“****Protecting Human Research Participants****”*** <http://phrp.nihtraining.com/users/login.php> For members who have come to SUNY Orange having completed a different training program while at another institution, that certification may be an acceptable substitute at the discretion of the IRB chair.
12. IRB members do not receive compensation for their service.
13. Liability coverage for IRB members is provided through the College’s liability insurance coverage, whether or not the IRB member is an employee of College.

# OPERATIONS OF THE IRB

## Meetings

1. IRB meetings are scheduled as required.
2. The place and time of meeting, agenda, and study material to be reviewed will be distributed to IRB members at least ten days prior to the meeting.
3. For applications requiring full IRB review, the IRB Chair assigns one primary reviewer and at least one secondary reviewer. The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s) possess valuable perspective on salient non-scientific aspects of the research. The assigned reviewers lead the discussion of that application during the formal meeting.
4. Minutes will be taken by the Vice Chair. In the absence of the Vice Chair the Chair will appoint a member of the IRB to take minutes. In the absence of the Chair, the Vice Chair will preside over the meeting and the minutes will be taken by a member of the IRB committee designated by the Vice Chair.

## Protocol for Full IRB Review Meeting

1. The minimum of five IRB members must be present to convene a full IRB review.
2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting.
3. Principal Investigators, including those who are also IRB members, should attend the meetings to offer information and answer questions about their protocols at a convened meeting, but may not be present during voting.
4. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If, during an IRB meeting, the Chair moves the meeting to executive session then any visitors will be asked to leave the room until the executive session has ended.

## Documentation

1. The IRB, in collaboration with the Office of Institutional Research, must maintain files that include a complete history of all IRB actions related to review, approval, or denial of a protocol, including continuing reviews, amendments and adverse event reports.
2. The IRB must retain all records regarding an application (including those which did not receive approval) for at least 3 years. For all applications that are approved and the research initiated, the IRB must retain all records regarding that research according to requirements of the funding agency, but at minimum for three (3) years after completion of the research.
3. The IRB must make all records available for inspection and copying by authorized representatives of the sponsoring Department or Agency, the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.
4. The IRB must prepare and/or maintain the following documents:
   1. Copies of all documents including but not limited to; research applications reviewed, scientific evaluations, approved sample consent documents, data safety monitoring board reports, progress reports submitted by investigators, and reports of injuries or adverse events to subjects.
   2. Minutes of all IRB meetings.
   3. Records of continuing review activities.
   4. Correspondence with Investigators - copies of all correspondence between the IRB and the investigators.
   5. IRB Committee Members - A list of the membership identified by name, earned degrees, representative capacity, indications of experience such as board certifications and licenses, sufficient to describe each member’s chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and SUNY Orange, such as full or part-time employee, member of governing panel or board, paid or unpaid consultant. Note that changes to IRB membership needs to be updated with OHRP by the IRB Chair.
   6. Written policies and procedures which the IRB will follow for :
      1. conducting initial and continuing review of research and for reporting its findings and actions to the Investigator and the institution.
      2. determining which projects require review more often than annually and which projects need verification from sources other than the investigators, indicating that no material changes have occurred since the previous IRB review.
      3. insuring prompt reporting to the IRB of proposed changes in a research activity, and for insuring that such changes in research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.
      4. insuring prompt reporting, appropriate institutional officials,

and the Department or Agency head of any unanticipated problems

involving risks to subjects or others, or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB.

* + 1. any suspension or termination of IRB approval.
  1. Statements of any new significant findings developed during the course of the research which may relate to the subject’s willingness to continue participation.
  2. Other correspondence or documents generated by the IRB.

1. All informed consent forms must be preserved by the investigator for three years after the completion of the research. Should the Principal Investigator leave SUNY Orange before three years, the signed consent forms are to be transferred to the IRB chairperson.

## Annual Report to VPAA

Each year the IRB will provide an annual report to the Vice President of Academic Affairs that includes a review of the activities and outcomes of the SUNY Orange IRB and recommendations to improve the process.

## Conflict of Interest

It is the responsibility of all IRB members to identify and avoid any situations in which they, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. It is the responsibility of the IRB members to inform the IRB Chairperson should they have a conflict of interest during review of any proposal.

## Training and Support to the Campus

An additional responsibility of the IRB at SUNY Orange will be to provide ongoing professional development for employees and students regarding the application and reporting process to the IRB. To comply with federal requirements, SUNY Orange requires mandatory and continuing education for all employees, students, investigators and research personnel involved with human participants. To be certified, one must complete the National Institutes of Health (NIH) Office of Extramural Research web –based training course, “Protecting Human Research Participants”. <http://phrp.nihtraining.com/users/login.php> This NIH Certification is valid for 2 years.

# IRB APPLICATION PROCESS

## How to Determine Under What Circumstances to Apply for IRB Approval

All activities that meet the definition of “research” with “human subjects” and that will contribute to generalizable knowledge are subject to IRB review. One must possess a firm understanding of the federal definition of the terms “human subjects” and “research”, in order to determine if the activity is a classroom project or research (see research vs classroom assignment). In addition, one must be aware of roles and responsibilities of a principal investigator.

**Definitions of Human Subjects & Private Information**

Pursuant to federal regulation, “human subject” is defined as “living individual(s) about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.” Therefore, only research activities involving data obtained through intervention or interaction with a living individual or involving identifiable private information regarding a living individual must be reviewed by the IRB.

1. Intervention includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes (for example, comparing test performance in a quiet vs noisy environment).
2. Interaction includes communication or interpersonal contact between an investigator and a subject (examples: interviews and surveys).
3. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (the identity of the subject is or may readily be ascertained by the Investigator or by association with the information) in order for obtaining the information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject regarding a third party.

## Definition of Research

Only certain activities involving human subjects qualify as “research” subject to the jurisdiction of the IRB. The federal regulations define “research” to mean “a systematic investigation (i.e. the gathering and analysis of information) designed to develop or contribute to generalizable knowledge”.

1. A major factor in determining whether an activity is research subject to IRB review depends upon the Investigator’s intent to “contribute to generalizable knowledge”, and whether there is a systematic design in advance, generally utilizing a scientific approach or protocol, for the defined purpose of contributing to generalizable knowledge.
2. If the Investigator intends to publish or disseminate the results, the activity will be viewed as intending to contribute to generalizable knowledge, and therefore constitutes research subject to the IRB’s jurisdiction. Activities that may result or be included in a thesis, dissertation, journal article, poster session, public speech, or presentation must be reviewed by the IRB.
3. If there is any possibility that the Investigator may want to publish or disseminate the resulting data in the future, then the protocol must be submitted for IRB review before subjects are recruited and data collected.
4. The use of a single human subject in research activities, such as a case study, can constitute research that is subject to IRB review and approval when there is a clear intent before recruiting or interacting with the subject to use systematically collected data that would not ordinarily be collected in the course of daily life in reporting and publishing a case study. As a general rule, when a series of subject observations are compiled in such a way as to allow possible extrapolation or generalization of the results from the reported cases, that activity constitutes research that must be reviewed by the IRB.

## Definition of Principal Investigator (PI) and Responsibilities

Research which is conducted by a SUNY Orange employee or student who initiates and/or conducts an investigation, alone or with others, is considered to be a SUNY Orange Principal Investigator (PI) even if the research occurs at a location for which the SUNY Orange IRB is not the IRB of record.

It is the PI’s responsibility to apply for SUNY Orange IRB approval. The PI assures the IRB that the principles, procedures and guidelines established in the protocol will be followed and agrees to allow the IRB access to pertinent records and research. The PI will present all information that will aid in evaluating the research for compliance with this policy. The PI is responsible for completing the periodic review and for retaining informed consent documents for a period of three years after completion of the project.

It is the Investigator’s responsibility:

* to apply for IRB approval,
* to keep the IRB informed of any problems involving change in risks to subjects or adverse events that result in a change to the conditions upon which approval was based.

An “Adverse Event” form must be submitted immediately to the IRB Chair if an adverse event occurs or any change to the risk occurs in the research being conducted.

* to inform the IRB of any changes in procedural design of the protocol

## Definition of Adverse Event

An adverse event is any undesirable and unintended, although not necessarily unexpected, effect of the research occurring in human subjects as a result of (a) the interventions and interactions used in the research; or (b) the collection of identifiable private information under the research. [Adapted from the 1993 OPRR IRB Guidebook]

An adverse advent can either be an expected or unexpected negative incident. Below is an example of an expected adverse advent which the PI should immediately report to the IRB chair using the “Adverse Event” form found on the IRB web site.

A PI is conducting a psychology study evaluating the factors that affect reaction times in response to auditory stimuli. In order to perform the reaction time measurements, subjects are placed in a small, windowless sound proof booth and asked to wear headphones. The research protocol and informed consent document describe claustrophobic reactions as one of the risks of the research. One subject enrolled in the research develops a severe anxiety reaction due to claustrophobia, resulting in the subject withdrawing from the research.

Unexpected adverse events include those events that are not expected given the nature of the research procedures and the subject population being studied; and suggest that the research places subjects at a greater risk of harm or discomfort related to the research than was previously known or recognized. The PI must report the event immediately to the IRB Chair using the “Adverse Event” form and the IRB may report this unexpected adverse event to Department of Health and Human Services. Below is an example of an unexpected adverse event.

A PI conducts a study in college students that involves completion of a detailed survey asking questions about early childhood experiences. The research was judged to involve no more than minimal risk and was approved by the IRB Chair under an expedited review procedure. During the completion of the survey, one student subject has a severe psychological reaction manifested by intense sadness, depressed mood, and suicidal ideation. The protocol and informed consent document for the research did not describe any risk of such negative psychological reactions. Upon further evaluation, the PI determines that the subject’s negative psychological reaction resulted from certain survey questions that triggered repressed memories of physical abuse as a child. The PI had not anticipated that such reactions would be triggered by the survey questions and did not include this information in the research protocol and informed consent document.

# Research vs. Classroom Assignment

## Classroom assignments that require IRB review

All activities that meet the definition of “research” with “human subjects” and that are conducted by students for a class project must be reviewed by the IRB. For example, activities that must be reviewed and approved by the IRB include all projects that involve human subjects and for which the research is designed to develop or contribute to generalizable knowledge and the findings are intended to be published in a thesis, dissertation, journal article, poster session, public speech, or public presentation.

## Classroom assignments that are exempt from IRB review

Courses of study at SUNY Orange which are designed to teach students about and to provide them with an opportunity to practice various research methods differ from research activities that would generally require IRB review in that the primary intent of the classroom project is for the student to become more knowledgeable about the research process. Additionally, such projects typically do not lead to generalizable knowledge and are not undertaken with that goal in mind. Therefore, simulations of research using human subjects and course-assigned data collection are not deemed to be research that is subject to IRB review so long as the activity meets the following requirements:

* 1. the activities are designed for educational purposes only
  2. the data will not be generalized or published outside the classroom
  3. the data will not result in an article, master’s thesis, doctoral dissertation, abstract, other publication or public presentation
  4. student volunteers or other participants are clearly informed that the activities are an instructional exercise and not actual research

## Faculty Responsibility

It is the responsibility of the faculty to determine, prior to assigning a project, whether the project is a classroom project or research. Faculty members are encouraged to review the IRB website and consult with a member of the IRB in making such a determination. Should a class project be conducted that meets the definition of research but does not receive IRB review and approval, the faculty member will be considered to have engaged in IRB noncompliance and may be personally liable. Research must be reviewed by the IRB prior to the start of the project. No data collected as a course assignment can be used for research purposes.

## Retroactive approval is not granted

IRB approval cannot be granted retroactively. Any data collected without IRB approval cannot be used for future theses, dissertations, abstracts, publications, posters, or outside of classroom presentations. It will need to be recollected if it is subsequently determined that the work is appropriate for a research project. Recollection of the data may delay a student’s completion of course assignments or theses and dissertations.

## Informed Consent

After the IRB reviews a proposal by assessing research protocol and human subject participation, the IRB turns to the consent process to insure that subjects are fully aware of the risks and the benefits and that they participate in the project voluntarily. The consent form is a key element in this review. “Informed Consent” means insuring that potential subjects and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent are found at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>

Sample consent forms; general consent, parent consent and student consent forms are on the IRB website.

## When to File a Research Application

An application for research must be approved by the IRB before an investigator starts to work on the project. The IRB approval must be granted before they begin to recruit subjects, since recruitment strategies are part of the review. The application and approval process may take months; therefore applications should be submitted well before your anticipated project start date. After reviewing the application and its supporting materials, the IRB may require revisions in the protocol. When the investigator revises a project, the IRB will review the project again to determine whether its concerns have been adequately addressed. A project may undergo several reviews before final approval. It is only after final approval that human subject recruitment may take place.

The type of research will determine the level of IRB review. Investigators should become familiar with the different levels of IRB review determined by subject risk. “Minimal subject risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”. If the research protocol does not qualify as “minimal risk” then a full IRB review is needed.

# Levels of IRB Review

Research projects are reviewed at one of three levels, according to the IRB’s determination of the project’s potential risk to the human subjects and the federal guidelines that define the categories of review, which are:

1. Exempt from Full IRB review
2. Expedited IRB review
3. Full IRB review

The PI may apply for one of these three levels of review, but the IRB Chair, not the principal investigator, ultimately determines the level of review after reviewing the application from the PI. Below are the descriptions of the three levels of review.

## Exempt from Full IRB Review

Research that involves only minimal risk to human subjects is sometimes exempt from full IRB committee review, but it is still subject to IRB review. “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”.

Researchers must file the application, ***Exempt*** ***from Full IRB Review Form***, (located on the IRB website) requesting that the IRB determine exempt status for a project by providing justification in the application. The IRB may also choose to waive the requirement to obtain a signed consent form for some or all subjects.

To qualify as exempt from full IRB review, research must fall into one of five federally-defined exempt categories. These categories present the lowest amount of risk to potential subjects because generally speaking they involve either collection of anonymous or publicly-available data, and qualify as minimal risk to subjects. Research that involves prisoners, pregnant women, fetuses, or neonates **does not** qualify for exempt review. Below are the exempt categories.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as; research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. The information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects and disclosure of the human subjects' responses outside the research could not place the subjects at risk of criminal or civil liability. **An exception to this exemption is research involving survey, interview procedures, or observation of public behavior involving human subjects under 18 years of age. One exemption for human subjects under 18 years of age is for research when the investigator(s) does not participate in the activities being observed or tested. Another exception is when subjects are public officials or candidates.**
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
4. Research and demonstration projects on public benefit or service programs which are designed to study, evaluate, or otherwise examine: procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, possible changes in methods or levels of payment for benefits or services under those programs.
5. Taste and food quality evaluation and consumer acceptance studies; if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Examples of research exempt from IRB Review

* Anonymous surveys or interviews
* Passive observation of public behavior without collection of identifiers
* Retrospective chart reviews with no recording of identifiers
* Analyses of discarded pathological specimens without identifiers

## Expedited IRB Review

An expedited review procedure consists of a review of research involving human subjects by the IRB chair or by one or more reviewers designated by the chairperson from among experienced members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. If the reviewer feels that the research does not qualify as an expedited review process, the PI is informed and has the opportunity to resubmit the research proposal for a full IRB review.

To qualify for expedited review, a research procedure must be limited to the [activities that are federally approved](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm) for expedited review and incur no more than *minimal risk* for participants, or be a *minor* change in previously approved (prior approval one year or less) research that involves *no additional risk* to the research subjects.

Researchers must file the application, *Expedited IRB Review Form*, requesting that the IRB determine expedited status for a project by providing justification in the application (located on the IRB website).

Research Categories for expedited review

1. Research on medical devices for which the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.  
     
   Examples: hair and nail clippings in a nondisfiguring manner; deciduous teeth at time of exfoliation, permanent teeth if routine patient care indicates a need for extraction, excreta and external secretions (including sweat), uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue, supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques, mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings, sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.   
     
   Examples: physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy, weighing or testing sensory acuity, magnetic resonance imaging, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography, moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: This listing refers only to research that is not exempt.)

Examples of Research:

* Surveys and interviews with collection of subject identifiers
* Collection of biological specimens (e.g., hair, saliva) for research by noninvasive means
* Collection of blood samples from healthy volunteers
* Studies of existing pathological specimens with subject identifiers

## Full IRB Review

A project that involves greater than minimal risk, or that involves subjects needing additional protection requires approval by a full IRB panel composed of members qualified to review research in that field. Researchers must file the application, ***Full IRB Review Form***, (located on the IRB website).

Research that requires full committee review includes:

1. Research that involves greater than minimal risk
2. Non-exempt research that involves children, prisoners, pregnant women, human fetuses, neonates or other vulnerable populations
3. Research that involves experimental drugs or devices
4. Research that involves invasive procedures
5. Research that involves deception - should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.
6. Survey research that involves sensitive questions or information about sexual practice or illegal behavior
7. Survey research or interview that is likely to be stressful for the subject

Examples of research:

* Survey about the transmission of AIDS
* Survey about the PTSD administered to veterans
* Observation of a child’s behavior with the principal investigator present in the child’s environment
* Dietary test of a high protein supplement in pregnant women

# Guidelines for Application Submission

* 1. All applicants must fill out an application for Human Subject Research according to the level of anticipated review by the IRB and supply all the supporting documentation: an abstract, consent form (if needed), and a copy of the Certificate of Completion from the National Institutes of Health (NIH) Office of Extramural Research.
     + - 1. All investigators and research personnel must complete the National Institutes of Health (NIH) Office of Extramural Research web –based training course, “Protecting Human Research Participants” prior to submitting their application. This free training course should take approximately three hours to complete. <http://phrp.nihtraining.com/users/login.php> When finished, download, save, and print your Certificate of Completion. The NIH certification is valid for 2 years. For investigators and research personnel who have come to SUNY Orange having completed a different training program, you may submit your training to be considered as an acceptable substitute at the discretion of the IRB chair. A brief description of the training, the name of the granting institution and a copy of the appropriate certification must be included in the submission.
         2. Application materials for Human Subject Research may be accessed on the College’s IRB website.
         3. In the application, the investigator assures the IRB that the principles, procedures and guidelines established in the document will be followed and agrees to allow the IRB access to pertinent records and research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance.
         4. The IRB shall have authority to determine which studies need verification from sources other than the investigators
         5. It is the responsibility of the PI to give each subject an explanation in response to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if, in the judgment of the IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period of time. There is an exception to this delay: In those cases in which it is unavoidable to mislead the subjects and/or in which it the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.
  2. Completed applications are to be electronically submitted to the administrative assistant in the Office of Associate Academic Vice Presidents.
  3. The administrative assistant reviews the application to insure all documents are completely filled out and attached. If the application is incomplete, it is returned to the investigator. Once an application is complete, the administrative assistant forwards the application to IRB chairperson.

# Procedures of the IRB for Application Review

1. The IRB Chairperson will review the application and determine the level of IRB review; exempt from full IRB review, expedited IRB review, or full IRB review.
   1. An exempt from full IRB review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more reviewers designated by the chairperson from among experienced members of the IRB.
   2. An expedited IRB review procedure consists of a review of research involving human subjects by the IRB chairperson and one more reviewer designated by the chairperson or by two IRB members designated by the chairperson from among experienced members of the IRB.
   3. A full IRB review procedure consists of a review of research involving human subjects by five members of the IRB designated by the chairperson.

1. In protocols exempt from full IRB review, the IRB Chair cannot “disapprove” a research protocol without requesting that another member of the IRB review the protocol.
2. The IRB Chair will inform the principal investigator of the Board’s actions in writing. Any disagreement between the PI and the IRB Chair will be resolved by the IRB.
3. All levels of the IRB review will use the same criteria.  In order to approve research the IRB shall determine that all of the following requirements are satisfied:
   1. Risks to subjects are minimized - Use of procedures which are consistent with sound research. That the risk profile of the proposed research study, including the type, probability, and expected level of severity of the potential adverse events that may result from the research are minimized.
   2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
   3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
   4. Informed consent will be obtained from each prospective subject or the subject's legally authorized representative.
   5. Informed consent will be appropriately documented and contain all information about risk.
   6. The research plan makes adequate provision for monitoring all data, including the type of data and adverse events to ensure the safety of subjects and who will be responsible for collecting and reporting this data, along with the frequency of monitoring & assessing the data.
   7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
   8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
4. The PI must be available to discuss the research protocol and/or consent forms at the discretion of the IRB

# Actions of the IRB

The IRB may take one of the following four actions in regard to the proposed research protocol and consent form: ***Approved, Approved with stipulations, Not approved, Deferred.*** All decisions will be sent to the PI by the IRB chairperson.

1. **Approved** means approved as submitted - When a protocol has been approved, the Chair completes the “Action of the IRB” form, signs and dates it, and distributes one copy of the form to each of the following: the principal investigator, the IRB files and, if appropriate, the performance site.
2. **Approved with stipulations** means conditions must be met before final approval is granted. If the protocol is approved subject to stipulations, then the Chair completes the “Action of the IRB” form, signs and dates it, and distributes it to the PI as a protocol approved with stipulations. The PI then must respond to the stipulations as indicated by the IRB. Upon receipt and approval of the responses, the restrictions are removed and the research protocol is then processed as an approved protocol and distributed as described above.
3. **Deferred action** means that the protocol or consent form was not sufficiently complete for the IRB to reach a final decision. In this case, the PI is notified by the IRB chairperson of the additional information requested by the IRB. The PI may be invited to attend an IRB meeting to present/clarify the information or the PI may have to revise the protocol and/or consult forms and resubmit the revised information.
4. **Not Approved** means approval is not granted and the research cannot take place. If the protocol is not approved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit the application for another review.

## Responsibility of Investigators upon Research Approval

1. PIs shall be informed at the time of protocol approval (both initial and continuing) that they must immediately bring to the attention of the IRB Chair any proposed changes, any adverse events, or any serious or continuing noncompliance in the program which may affect the status of the research as it relates to the use of human subjects.
2. PIs shall be informed at the time of protocol approval (both initial and continuing) that changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects
3. PIs shall be informed at the time of protocol approval (both initial and continuing) the frequency of periodic review reporting to the IRB.

## Appeals

The PI of any proposal may appeal the decision of the IRB when a protocol has been disapproved or approved with stipulations and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc* committee of three or more faculty and/or consultants to review the protocol a second time. The *ad hoc* committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established herein and the decision of the *ad hoc* committee will be referred to the IRB. The final decision regarding the protocol will be made by the IRB. The PI will be promptly notified of actions of the *ad hoc* committee and final action by the IRB. Non approval by the IRB following an appeal cannot be overridden by any institutional official or administrator.

## Periodic Review

The IRB may conduct periodic review of research at intervals appropriate to the degree of risk, but not less than once per year. The PI will be informed of the due dates for periodic review on their approved Human Subject Research form. The PI must complete the Periodic Review of Continuing Research Form which can be found on the IRB website. A brief summary of the activities from the research starting date to the periodic review request date, or a summary of activities from the previous review date to this current review date shall also accompany the Periodic Review documentation. The IRB shall have authority request a periodic review from other than the PI.

## Extension of Research

Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project, subject to the PI filing the Extension of Research Form, (located on IRB website) within 30 days before the IRB approval period expires. However, if an investigator has failed to file an Extension of Research Form to the IRB the research must stop, unless the IRB Chair or Vice Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the protocol will be considered closed and enrollment of new subjects cannot occur nor can any data collected after the expiration date be used for research purposes.

## Criteria for Periodic Review and Extension of Research by IRB

When a Periodic Review or a request for Extension of Research is submitted, the IRB shall consider the following: changes to the research, protocol deviations and violations; adverse event reports; reports of unanticipated problems involving risks to subjects, and investigator compliance. The PI will be notified of the action taken (e.g., Approved, Approved Subject to Stipulation, Not Approved, or Deferred)

If the protocol and/or any other change to the research project have been made and have not been amended since the last review, the PI will be requested to submit a new protocol incorporating these amendments. The IRB shall have authority to determine which studies need verification from sources other than the investigators.

## Criteria for Review of Adverse Events by IRB

Expected Adverse Event

The IRB Chair and/or another member designated by the IRB chair reviews the Adverse Event Report to determine if this event corresponds to the description of the expected adverse event by reviewing the research protocol and informed consent document. If the adverse event corresponds with the description in the protocol and informed consent document, then the adverse event form is kept on record. If the IRB Chair or designee does not think the expected adverse event is accurately described in the research protocol or consent form, the IRB chair (or designee) requests in writing that the PI propose modifications with the study protocol and/or consent form and submit a response of the necessary additional modifications for review by the IRB. The review process will be the same as an Expedited IRB Review.

Unexpected Adverse Event

The IRB Chair and/or another member designated by the IRB chair will reanalyze the risk versus potential benefit of the research as a result of the occurrence of an adverse event.

The IRB Chair or designee will review the information provided by the PI regarding suggested changes in the research protocol, modification of inclusion or exclusion criteria to mitigate the newly identified risks, implementation of additional monitoring procedures of subjects, termination of enrollment of new subjects, modification of informed consent documents to include a description of newly recognized risks, and provision of additional information about newly recognized risks to previously enrolled subjects. If the proposed changes are minor, then an Expedited IRB Review will take place. If any of the proposed modifications represent more than a minor change, or if the IRB chair or designee determines for any reason that these proposed changes should not be approved under an Expedited Review procedure, the proposed modifications will be subjected to a Full IRB Review. The IRB has the authority to suspend or terminate approved research that has been associated with unexpected adverse events to subjects. Any suspension or termination of approval must include a statement describing the reasons for the IRB’s action and must be reported promptly to the PI, and the VPAA.

## Failure to Submit Project for IRB Review

If an investigator knowingly engages in activities that qualify as research that is subject to IRB review without obtaining prior approval by the IRB, the data that are collected and the results are deemed to be not usable and the research must stop immediately. The investigator would be personally liable for any risk of discomfort the subjects experienced.

If an investigator commences a project and later finds that the data gathered could contribute to generalizable knowledge or that he or she may wish to publicize the results, the investigator must submit a proposal to the IRB office for review as soon as possible. This would not guarantee approval of the research. Approval would depend on the kind of research engaged in, the risks, the appropriateness and the intent of the investigation. Possible outcomes may include, but not be limited to, frequent reviews of the ongoing research, not allowing the research to be published, or disapproval.