UNCW	**03.380**	**Institutional Review Board Policy**
Authority:		Provost and Vice Chancellor for Academic Affairs
History:		Revised January 21, 2019; revised May 9, 2018; revised September 1, 2015; revised October 1, 2008; revised October 15, 2007; established October 4, 2006
Source of Authority:		CFR Title 45 Part 46, Protection of Human Subjects
Related Policies:		UNCW Policy 03.230, Conflict of Interest or Commitment UNCW Policy 03.300, Research Misconduct
Responsible Office(s):		UNCW Research Integrity Office

I. Purpose and Applicability

The purpose of this policy is to satisfy requirements of CFR Title 45 Part 46 and to provide clarification and interpretation of that law to UNCW Institutional Review Board (IRB) members, administrators and researchers.

This policy applies to all funded or unfunded activities involving human subjects research as defined below, conducted by any UNCW faculty, staff or student, or by any researcher from an external institution collaborating with UNCW researchers or using UNCW facilities or populations.

Members of the campus community seeking guidance on whether a particular activity involves research with human subjects or not may: refer to the Decision Charts available on the Human Subjects Research website (http://uncw.edu/sparc/integrity/irb.html); refer to the ***Activities Not Requiring IRB Review Procedures*** (SOP 1.1); consult with the IRB chair; or contact the Research Integrity team at IRB@uncw.edu.

II. UNCW IRB Administration

The UNCW Research Integrity Office (RIO) director or designee will maintain current contact information on the Human Subjects Research website (http://uncw.edu/sparc/integrity/irb.html).

III. Important Definitions

A. Adverse Event – an untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, physical or psychological, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

B. Belmont Report – a statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

C. Deception – knowingly providing false information to research subjects or intentionally misleading research subjects about some key aspect of the research.

D. Human subject – a living individual, about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR § 46.102(e)(1)(i) and (ii))
   1. Intervention – includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
   2. Interaction – includes communication or interpersonal contact between investigator and subject.
   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 that has been provided for specific purposes by an individual and that that the individual can reasonably expect will not be made public (e.g., a medical record).
   4. Identifiable private information – private information for which the identity of a subject is or may readily be ascertained by the investigator or associated with the information.
   5. Identifiable biospecimens – a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

E. Incomplete disclosure – withholding information about the specific purpose, nature, or other aspect of a research study from research subjects.

F. Informed Consent – A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

G. Legally Authorized Representative – an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

H. Minimal risk – the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR § 46.102(i))

I. Principal Investigator (PI) – the member of a research team who is the lead researcher for the project. If a student is the primary researcher on a project, the student's faculty advisor must be listed in the IRB application and is ultimately responsible for ensuring the requirements of this policy are met during the conduct of the study.

J. Research – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are supported under a program that is considered research for other purposes. (45 CFR § 46.102(l))
   1. Systematic Investigation – a cohesive approach involving data collection (quantitative or qualitative) from one or more individuals and analysis to address a question or test a hypothesis.
   2. Generalizable Knowledge – the results or outcomes gained from systematic investigation are expected to contribute to a theoretical framework of an established body of knowledge, be viewed in some way as relevant to a larger population beyond the data collection or population studied, and intended to be replicated in other settings.

K. Quorum – the presence of a majority of members at a convened meeting, including at least one member whose primary concerns are in nonscientific areas. (45 CFR § 46.108(b))

L. Researcher – any member of a research team.

M. Unanticipated Problem – any incident, experience, or outcome that is unexpected in terms of its nature, severity or frequency given the research procedures that are described in the protocol-related materials and the characteristics of the subject population being studied, and is related or possibly related to participation in the research, and suggests that the research places subjects or others at greater risk of harm (including physical, economic, or social harm) than was previously known or recognized.

IV. UNCW IRB Membership

The UNCW IRB will be constituted in accordance with 45 CFR § 46.107, as detailed in the ***Membership Selection, Resignation and Removal Procedures*** (SOP #4.1). Established members in good standing who have fulfilled their terms have the option of serving an additional term.

A. Appointment of IRB Chair

The Institutional Official (IO) as designated on the Federalwide Assurance to the Office of Human Research Protection (OHRP) appoints an IRB chair for a specified term, as agreed to by the parties, with the option of reappointment. The IRB chair should be a current IRB member and a tenure-track faculty member.

B. Appointment of IRB Co-Chair

The IO may appoint an IRB co-chair for a specified term, as agreed to by the parties. The IRB co-chair should be a current IRB member and a tenure-track faculty member.

C. Alternate Members

Alternate members have the same responsibilities as full members except that they attend meetings only when needed to vote in place of a full member. Alternate members in good standing may be offered full member terms as openings become available.

D. Active Membership Required

A member may be considered inactive if he or she is not present at three consecutive, regularly scheduled meetings, or if he or she has not completed the required training. The chancellor may appoint replacements for inactive members. IRB meetings will be scheduled at times when the most members are available.

E. Removal of Members from the Committee

Members may resign or be removed from the committee in accordance with the Member Resignation/Removal Procedures. Replacement members may also be appointed in accordance with those procedures.

V. UNCW IRB Responsibilities

IRB members are responsible for ensuring that all human subjects research conducted by UNCW researchers is ethical and consistent with the three ethical principles delineated in the Belmont Report: respect for persons, beneficence, and justice. The IRB is responsible for being properly trained, reviewing protocols, consents, adverse events and noncompliance, investigating concerns for human subject welfare, communicating with appropriate regulatory and funding agencies, and monitoring post-approval compliance.

A. Training

All members of the UNCW IRB must complete the Basic Course for Human Research Protections course and IRB Member module through the online CITI Program or equivalent training as determined by the RIO director prior to conducting IRB business. Members should also familiarize themselves with the Belmont Report and its principles.

B. Protocol Review

The UNCW IRB will conduct reviews of new and ongoing human subjects research in accordance with 45 CFR § 46.109 and 45 CFR § 46.111, as detailed in the ***Exempt Research Procedures*** (SOP #5.1), ***Expedited Review Procedures*** (SOP #5.2), and ***Full Board Review Procedures*** (SOP (#5.3).

1. Protocol review includes approving, requiring modifications to, or disapproving research.

2. Continuing review of all approved research will be conducted in accordance with applicable regulations and be based on the degree of risk of the research.

C. Informed Consent

The IRB must ensure that the process for obtaining and forms for documenting informed consent are in accordance with 45 CFR § 46.116 – § 46.117.

D. PI Notification

The IRB must notify PIs in writing of IRB decisions to approve or disapprove research.

E. Meetings

1. The UNCW IRB will schedule a standing meeting once each month during the academic year (September through May) to consider new and continuing research applications that require full IRB review. The dates of these standing meetings will be announced on the Human Subjects Research website (http://uncw.edu/sparc/integrity/irb.html). The IRB may cancel and/or reschedule meetings when a quorum of members is not available or when no items have been submitted by the posted submission deadline that require full board review.

2. IRB meetings are open to the public to the extent allowed under North Carolina's Open Meetings Act.

3. As required by 45 CFR § 46.108, initial and continuing reviews of research are conducted by the IRB at convened meetings during which a majority of the members of the IRB are present (i.e., a quorum), including at least one member whose primary concerns are in nonscientific areas, except where expedited review is appropriate. Approval of research is by a majority vote of this quorum. Should the quorum fail during a meeting (*e.g.*, loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored.

F. Retention of IRB Records

1. General Responsibilities

The IRB is responsible for keeping adequate records of its members, research review procedures, minutes of IRB meetings, correspondence with researchers, and review of research. Records must be maintained in accordance with 45 CFR § 46.115, and must be accessible for inspection and copying by authorized representatives of the university and the U.S. Department of Health and Human Services (DHHS), and by

the public to the extent allowed under North Carolina law, at reasonable times and in a reasonable manner.

2. IRB Meeting Minutes

The minutes of IRB meetings will record the members who attended the meeting, actions taken at the meeting, the outcome of the vote on research protocols including the numbers of members voting for or against approval and abstaining, the basis for requiring any modifications or revisions in research procedures or the informed consent process or forms, documentation of any specific findings required by the federal regulations, and a written summary of the discussion of controversial issues and their resolution.

G. Registering IRB & Updating Assurance

The UNCW IRB must register with OHRP and update and renew UNCW's Federalwide Assurance (FWA) with the DHHS.

VI. Researcher Responsibilities

Researchers are responsible for designing and implementing ethical human subject research, consistent with the three principles delineated in the Belmont Report: respect for persons, beneficence, and justice.
They must also comply with all applicable federal regulations impacting the protection of human subjects, as well as all applicable UNCW policies and standard operating procedures (SOPs), and IRB decisions, conditions, and requirements. Researchers are responsible for being properly trained, preparing timely research applications and implementing them as approved, retaining research records, and reporting to the IRB. Researchers should refer to the relevant IRB policies which follow, and SOPs posted on the Human Subjects Research website (http://uncw.edu/sparc/integrity/irb.html).

A. Training

All persons (faculty, staff or students) involved in the design and/or conduct of research projects involving human subjects must receive the training described in the ***Training Requirements Procedures*** (SOP #6.1) and submit documentation accordingly. In particular, all individuals who obtain informed consent from research participants must have completed the required training.

B. Submission of Forms to the IRB

PIs are responsible for ensuring that a thorough and accurate description of their research activities involving human subjects, and any supporting documentation, are submitted to and approved by the IRB using the online system designated by the IRB prior to initiating any human subject research activities. The RIO director or designee will maintain a link to this system on the Human Subjects Research website (http://uncw.edu/sparc/integrity/irb.html).

C. Research Involving Special Procedures

1. Research Using Online Sources

   Research may be conducted using electronic sources such as social networking sites (Facebook, Twitter, etc.) or online marketplaces (Craigslist, eBay, etc.) provided the researcher observe the identification and privacy requirements set forth in the ***Online Research Procedures*** (SOP #6.2).

2. Research Using Anonymous Surveys or Questionnaires

   Researchers are encouraged to design studies that minimize risks to subjects, including studies using surveys/questionnaires that allow subjects to respond anonymously. Researchers who employ this method may qualify for an exemption, provided certain procedures identified in the ***Anonymous Survey/Questionnaire Procedures*** (SOP #6.3) are followed.

3. Research Involving Other Institutions

   Research that involves recruiting non-UNCW populations may require additional permissions if subjects are recruited at facilities such as public schools, other universities or colleges, hospitals or other medical facilities, child care centers, nursing homes or other similar locations where subjects may have a reasonable expectation of privacy. Additional information can be found in the ***Research Involving Other Institutions Procedures*** (SOP #6.4).

4. Research Using Non-U.S. Populations

   When research involves recruiting non-U.S. populations in foreign countries, the UNCW IRB will determine if there are any local regulations that may be applicable to the study under review. If so, researchers may need to obtain additional approvals from local authorities prior to proceeding with the research. Additional information on conducting research in international locations can be found in the ***International Research Procedures*** (SOP #6.5).

5. Research Involving Deception and/or Incomplete Disclosure

   a. Researchers who plan to use deception and/or incomplete disclosure as a method must follow the procedures outlined in the ***Use of Deception in Human Subjects Research Procedures*** (SOP #6.6).

   b. Researchers may not deceive subjects about significant aspects of the research that would affect their willingness to participate. If deception on significant aspects of research is necessary, researchers must provide subjects with an opportunity to withdraw the data collected from them.

c. Researchers may not use deceptive techniques to lure subjects to participate in research.

d. Researchers may not deceive or not fully inform subjects about aspects of the research that are anticipated to cause physical or emotional harm, or which pose greater than minimal risk to subjects.

e. The benefit of the research involving deception and/or incomplete disclosure will sufficiently outweigh any risks that deception or incomplete disclosure may create.

f. Deception/incomplete disclosure will be explained to participants through debriefing as early as feasible. Requests to delay debriefing are subject to approval by the IRB.

E. Implementation of Research

Research must be implemented as approved except where necessary to eliminate apparent immediate hazards to the subjects.

F. Reporting

1. Continuing Review

The PI is responsible for reporting to the IRB the progress of research approved by the full board, as often as and in the manner prescribed by the IRB, but no less than once per year.

2. Adverse Events and Unanticipated Problems

The PI is obligated to eliminate apparent immediate hazards to all subjects and others. Any unanticipated problems involving risks to subjects or others, regardless of causality, must be reported as specified in the ***Identifying and Reporting Adverse Events and Unanticipated Problems Procedures*** (SOP #6.7) to the IRB by the PI or, in the absence of the PI, the responsible person designated on the protocol.

a. Temporary Suspension of Protocol

If the IRB chair believes the event provides information that may relate to subjects' willingness to participate or continue participation in the project, the IRB chair may temporarily suspend the protocol until a further decision can be reached, and appropriate information can be relayed to the research participants. Full IRB review will be used if a suspension is issued, the risk is determined to be significant, or at the request of the IRB chair or IO.

b. Investigation of Research Project

The IRB chair, IO, or full IRB may request an investigation of a research project. The IRB chair will designate an investigation team to investigate the research project and submit a report to the IRB within two (2) weeks.

3. Any decision made by another IRB or oversight board, such as a Data Safety Monitoring Board, must be relayed to the UNCW IRB within five (5) business days of notification.

4. Protocol Closure

   The PI must notify the IRB upon termination of the study, departure of the PI from the institution, and/or change in the PI for the study.

G. Informed Consent and Assent/Permission Requirements for Non-exempt Research

1. General Requirements

   a. UNCW recognizes that informed consent is a process, not a form. Researchers must:
      i. Provide prospective subjects and/or their legally authorized representatives (LARs) with information that a reasonable person would want to have in order to make an informed decision about whether or not to participate in the study.
      ii. Organize the informed consent information in a manner that facilitates comprehension.
      iii. Provide prospective subjects and/or their LARs with an opportunity to discuss the information provided on the consent form.
      iv. Ensure subjects and/or their LARs understand the information provided to them.

   b. Researchers must obtain and document informed consent and assent/permission in accordance with federal regulations, the ***Informed Consent Procedures*** (SOP #6.8), and as approved by the IRB.

2. Criteria for waiving or altering the informed consent requirements

   a. The IRB may consider requests to alter the standard consent process in accordance with 45 CFR § 46.116(e), § 46.116(f), and § 46.408(a), (b) and (c).

   b. The IRB chair may approve waivers or alterations to consent forms for research projects reviewed under expedited review.

3. Recruitment and Remuneration

   a. Recruitment materials should provide enough information about the research for potential participants to make an informed decision about whether or not to contact the researcher. The IRB chair or designee will review all recruitment

materials for expedited reviews. The convened IRB will consider recruitment materials for studies requiring full review.

b. Remuneration should be reasonable in relation to the specific population and should not be so great to be considered coercive. Remuneration must be fully described on the consent or assent/permission form.

H. Retention of Records

1. PIs are responsible for retaining all communication with the IRB, all signed, informed consent and assent/permission forms, and all relevant documentation, in the manner approved by the IRB, for at least 3 years after completion of the research.

2. All records must be accessible for inspection and copying by authorized representatives of the University and of the DHHS at reasonable times and in a reasonable manner.

VII. Categories of Research Review at UNCW

Only the IRB chair or designee can determine the category of research. Researchers cannot assume any research activities with human subjects do not require IRB review. Prior to determining the category of research, the IRB chair or designee will be responsible for determining whether or not a project is "research" and if the research involves human subjects.

If these criteria are met, the chair or designee determines whether an application to conduct human subjects research falls under the exempt review category or requires expedited or full review based on the criteria in 45 CFR § 46.101 *et seq*.

A. Incomplete Submissions

The chair or designate will notify PIs of incomplete applications. If the application remains incomplete after thirty (30) calendar days from notification, the IRB may remove it from the review queue.

B. Exempt Review

1. Research in the category of exempt review consists of those activities specified in 45 CFR § 46.104.

2. Studies involving the use of deception and/or incomplete disclosure do not qualify for exempt review even if all other aspects of the study qualify for an exemption.

3. The IRB will conduct exemption determinations in accordance with the ***Exempt Research Procedures*** (SOP #5.1).

C. Expedited Review

Expedited review covers research that poses no more than minimal risk to human subjects and/or minor changes in previously approved research that was subject to full board review. "Minimal risk" is the risk encountered in everyday life and is further defined in Section III.H. Specifically, expedited review may be employed for those categories of research activities established by DHHS, as authorized by 45 CFR § 46.110.

1. Research may be approved by expedited review but not disapproved. If the reviewer is unable to approve the protocol as submitted or with modifications, the reviewer must request full review by the IRB.

2. All members of the IRB will be notified electronically of all applications approved by expedited review and will be able to review the relevant application forms upon request.

3. The IRB will conduct expedited reviews in accordance with the ***Expedited Review Procedures*** (SOP #5.2).

D. Full Review

Research that does not meet the criteria for exempt or expedited review must receive full review from the IRB in accordance with the ***Full Board Review of Applications to Conduct Human Subjects Research Procedures*** (SOP #5.3).

E. Special Consideration for Vulnerable Populations

1. Research at UNCW on vulnerable populations, such as minors under age 18, prisoners, decisionally-impaired persons, and individuals in abusive relationships, will receive careful consideration to be certain that there are adequate procedures in place to protect these vulnerable subjects, in accordance with 45 CFR Part 46, Subparts B, C, and D, as applicable.

2. All research involving prisoners must be reviewed at a convened meeting with a prisoner representative present to evaluate the project for coercive situations or other issues that may arise from a prisoner perspective.

3. Although research that involves minors under the age of 18 may fall under the categories of exempt or expedited review, special attention will be paid to the ways in which both parental permission and the minor's assent are obtained and documented.

4. Research with decisionally-impaired persons will require special attention regarding both surrogate consent and participant assent.

F. Review Results

Following IRB review the PI will be notified in writing as soon as possible of the results of the review and the type of review conducted.

1. Protocol Approval

   IRB approvals are generally effective for one year, unless the IRB determines that a shorter approval period is warranted due to the risks of the study or issues of noncompliance, or unless the protocol was approved as exempt.

2. Modifications and Clarifications

   a. The IRB may grant approval contingent upon modifications to the research procedures or the informed consent process form. The IRB will contact the PI and inform the PI of the required modifications. It is the responsibility of the individual PI to make these changes and forward revised procedures and consent forms, when appropriate, to the IRB.

   b. The recruitment of participants and the gathering of data cannot begin until the IRB or IRB chair, as appropriate, approves such modifications. Once the modifications are approved the PI will be notified in writing.

   c. When the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under 45 CFR § 46.111, IRB approval of the proposed research may be deferred, pending subsequent review by the convened IRB of responsive material.

   d. When the convened IRB stipulates specific revisions requiring simple alterations by the PI, the IRB chair or designate may subsequently approve the revised research protocol on behalf of the IRB under an expedited review procedure. In this case, the IRB may vote to permit the IRB chair to approve the required modifications.

3. Protocol Disapproval

   If the protocol is disapproved, the IRB will notify the PI in writing of the reason(s). The IRB will allow the PI an opportunity to respond in person or in writing to the concerns of the IRB that led to disapproval. Following the PI's response, the IRB will vote on the protocol again as soon as possible or at the next regularly scheduled meeting.

G. Continuing Review (Annual Renewal)

1. Continuing review will be substantive and meaningful.

2. Continuing review will be conducted in accordance with 45 CFR § 46.109(e), 46.109(f), and § 46.115(3).

3. If the IRB determines that continuing review is required for research that otherwise would not require continuing review, the IRB shall prepare and maintain records showing the rationale for this decision.

4. Approval of Continuing Review

   If the protocol is approved for continuation, the IRB will notify the PI in writing of the new approval and expiration dates, and, if applicable, the IRB will provide the PI with an updated, stamped, and initialed consent and/or assent-permission form. Copies of this stamped document must be used when making copies to distribute to subjects.

H. Review of Protocol Modifications

All proposed modifications to research procedures, the informed consent process, or the forms used to document informed consent or assent/permission for research that has already been approved must be submitted to and approved by the IRB prior to the PI implementing any changes to approved procedures.

I. Protocol Closure

All expedited and full review protocols must request protocol termination. This practice ensures that the IRB is aware of all research activities and any problems that were encountered, and documents that the research has ended and no more renewals are necessary, when applicable.

VIII. Requirements For the Use of Protected Health Information (PHI) in Research

A. Overview

The Health Insurance Portability and Accountability Act (HIPAA) and corresponding federal privacy regulations govern the disclosure of personally identifiable health information, or PHI, from health care providers. Neither UNCW nor any of its individual units is a "covered entity" under HIPAA, and thus is not required to comply with HIPAA regulations applicable to covered entities. Likewise, most researchers are not themselves covered entities, because they do not maintain or transmit health data for purposes of treatment, payment, or health care operations. Health data that a researcher obtains directly from research participants, rather than from covered entities, is also not subject to HIPAA.

B. Scope

This Section VIII applies where UNCW researchers are receiving PHI from HIPAA covered entities. The HIPAA Privacy Rule governs the circumstances under which covered entities can disclose PHI to researchers. In those instances, the researcher may be required to meet certain privacy conditions before using PHI in research and/or cause UNCW to enter into a Business Associate Agreement. In all instances where a researcher

wishes to receive PHI from a HIPAA covered entity, the researcher must consult with the RIO director prior to formalizing any arrangement.

C. De-identified PHI

De-identified PHI is not subject to the HIPAA Privacy Rule. Accordingly, if a researcher is using de-identified PHI obtained from a covered entity, there is no additional requirement for privacy of the data. In order to qualify as de-identified PHI, the federal regulations (45 CFR §164.514) require the removal of over eighteen criteria. The covered entity that is disclosing the information to the researcher is required to ensure that the criteria are removed prior to releasing the PHI.

D. Individually Identifiable PHI

If a researcher intends to receive individually identifiable PHI, the IRB strongly recommends that the researcher review HIPAA resources available on the DHHS website (http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/). A disclosing covered entity may require a researcher to complete necessary HIPAA education and training requirements prior to handling PHI. In addition, the researcher must make one of the following assurances to UNCW's IRB:

1. The researcher will obtain individual authorization from subjects;

    a. The authorizations will either be standard authorizations used by the covered entity or custom authorizations created by the researcher that comply with HIPAA regulations.

    b. The authorization may be included in the informed consent document or may be a separate document. If included in the informed consent document, the authorization must still provide all elements required by HIPAA regulations.

2. The researcher will obtain a limited data set with a Data Use Agreement;

3. The researcher will obtain a waiver of authorization from the covered entity's IRB or privacy board. A copy of the documentation of the alteration or waiver of authorization signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable, must be provided to UNCW's IRB; or

4. The researcher is obtaining PHI on deceased people only. The researcher may be required by the covered entity to provide documentation that the disclosure is for research purposes only and that the disclosure is necessary in order to conduct the research. The covered entity may also require the researcher to provide documentation of the deaths of the individuals whose PHI is sought.

E. Business Associate Agreements

When a UNCW researcher is contracted by a covered entity to conduct certain functions on behalf of the covered entity, such as evaluating a program operated by the covered entity, the researcher may enter into a Business Associate Agreement (BAA) with the covered entity prior to the covered entity disclosing PHI to the researcher. The researcher must notify the RIO director at the earliest opportunity of his or her intent to enter into a BAA. The RIO director will coordinate with IT Security, the Office of General Counsel, and/or the HIPAA Compliance Committee, as appropriate, to ensure any administrative, technical, and/or physical safeguards required under HIPAA are met.

IX. Conflicts of Interest

A. Introduction

Conflicts of interest can arise in the conduct of research when financial or other personal considerations appear to or have the potential to compromise a researcher's objectivity in performing research activities. The IRB shall evaluate conflicts of interest in accordance with the ***Conflict of Interest Evaluation Procedures*** (SOP #9.1). In the event that a conflict of interest is present and must be managed, the IRB may impose certain conditions or restrictions on the PI and/or the research.

B. Summary of University Policy

The University Policy on Conflicts of Interest and Commitment specifically includes research activities in its definition and examples of "conflict of interest." According to university policy, subject employees must disclose annually certain financial and other information that might indicate a conflict of interest. Primary review and monitoring of activities related to conflict of interest are the responsibility of the employee's supervisor.

X. Research Audit

The full IRB or the IRB chair may request an audit of any study that has been approved by the IRB. Internal Audit or the Chancellor can also initiate an audit randomly, as part of an investigation, or for any other reason.

Research audits shall be conducted in accordance with the ***Audit of Human Subjects Research Activities Procedures*** (SOP #10.1). The PI is expected to cooperate fully with the IRB or other auditing party. In the event of findings of acts of noncompliance or activities that may jeopardize the welfare of human subjects or others, PIs may be asked to respond and outside agencies may be notified as required.

XI. Noncompliance with IRB Policies

A. Unapproved Research

1. Research conducted without IRB approval must stop until the PI obtains IRB approval.

2. IRB approval cannot be granted for research that has already been completed.

B. Findings of Noncompliance

Upon finding that a PI or any member of the research team has not complied with institutional policy regarding the protection of human subjects, the IRB chair will determine whether the violation is minor or major and proceed in accordance with the ***Findings of Noncompliance Procedures*** (SOP #11.1). Consequences for findings of noncompliance may include, but are not limited to, submission of a plan to correct the noncompliance, suspension of the protocol, termination of the protocol, and/or barring the researcher from conducting further research at UNCW.

XII. Reporting Deficiencies In Human Subjects Protections

Any serious or continuing noncompliance must be reported immediately. Any individual who is concerned about the conduct of research involving human subjects should promptly notify the IRB or RIO. Contact information for IRB staff and administration is maintained on the IRB website (http://uncw.edu/sparc/integrity/irb.html). Complaints may be filed anonymously. All complaints will be thoroughly investigated by the IRB or as appropriate, referred to the Associate Provost for Research for investigation under the university's Research Misconduct Policy.