Authority: Provost and Vice-Chancellor for Academic Affairs

History: October 4, 2006, October 15, 2007, October 1, 2008

Source of Authority: CFR Title 45 Part 46, Protection of Human Subjects

Related Policies: UNCW Conflict of Interest Policy
UNCW Research Misconduct Policy

Responsible Office(s): Research Services and Sponsored Programs

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.

II. UNCW IRB ADMINISTRATION

A. IRB Administration Location

Office of Research Services and Sponsored Programs (ORSSP)
B. Contact Information

Phone Number: 910-962-7774
Institutional Official: Dr. Robert Roer
IRB Chair: Dr. Candace Gauthier
Human Protections Administrator & Regulatory Compliance Officer: Leanne Prete

III. IMPORTANT DEFINITIONS

A. 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 HHS policy, whether or not they are supported under a program that is considered research for other purposes. (45 CFR46.102 (d))

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 that may be published, archived, presented, or viewed in some way as relevant beyond the specific participant population

B. Human subject - a living individual, about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information. (45 CFR46.102 (f)(1)(2))

C. Researcher – any member of a research team.

D. Principal Investigator (PI) – the member of a research team who is ultimately responsible for the project. The PI may not be a student. If a student is the primary researcher on a project, the student’s faculty advisor may serve as the PI.
E. 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 CFR46.102 (i))

F. Identifiable private information - information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonable expect will not be made public (for example, a medical record). (45 CFR46.102 (f)(2))

G. 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.


IV. UNCW IRB MEMBERSHIP

The chancellor receives a list of interested individuals for committee membership from the faculty senate by July 1 each year. Upon receipt of this list, the chancellor contacts the institutional official (IO) for recommendations based on the needs of the committee as set forth below. Established members in good standing who have fulfilled their terms have the option of serving an additional term. The chancellor appoints IRB members by August 1 for a two-year term based upon the IO’s recommendations. Pursuant to the Code of Federal Regulations Title 45 Part 46, the IRB must consist of at least five members of varying backgrounds.

A. Qualification of Members
1. The members must be sufficiently qualified, not solely of one profession, and reflect the gender, ethnic, racial, and cultural diversity of the University.

2. There must be at least one non-scientist IRB member and one member who is not affiliated with UNCW.

3. IRB members must be knowledgeable about the local research context.

4. The IRB must be sufficiently qualified through the experience and expertise and diversity of its members, including race, gender, cultural background, and sensitivity to such issues as community attitudes to promote respect for its advice and counsel.

5. The chancellor appoints members to the committee who represent various perspectives, interests, and beliefs.

6. IRB members must also possess expertise on “vulnerable populations” or consult outside experts when necessary.

B. Appointment of IRB Chair

The IO appoints an IRB chair for a one-year term with the option of reappointment. The IRB chair should be a current IRB member and a tenured faculty member.

The regulatory compliance officer (RCO) contacts IRB members each year in the spring to solicit input on the chair’s performance. The RCO contacts the current chair to determine if the chair is willing to serve an additional term. The RCO provides the IO with feedback regarding reappointment.

C. Appointment of IRB Co-Chair
The IO appoints an IRB co-chair for a one-year term. The IRB co-chair should be a current IRB member and a tenured faculty member.

The regulatory compliance officer (RCO) contacts IRB members each year in the spring to solicit nominees for co-chair and provides the IO with feedback.

D. Alternate Members

Alternate members in good standing may be offered full member terms as openings become available.

E. 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.

F. Removal of Members from the Committee

1. Resignation of Member

If a member needs to resign from the committee before the end of the member's term, the member must notify the regulatory compliance officer (RCO) as soon as the member makes the decision, as resignation could impact the committee's ability to conduct business depending on the designation of the member.

2. Member Termination

If the RCO, chair and/or IO deem it to be in the best interest of the committee to remove a member from the committee due to the member's lack of cooperation, lack of participation, non-compliance with IRB policies, or other issue, after failed
intervention by the RCO and/or chair to alter the issue, the IO will send the member a written notice of membership termination with reasons for the termination. If the terminated member is also a faculty member, the IO will copy the chancellor and the chair of the department to which the member reports. If needed the IO may recommend to the chancellor a new member to replace the terminated member. If the terminated member is also the IRB chair, the IO may appoint an interim chair until nominations for a new chair can be solicited from the committee and formally appointed by the chancellor.

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 principals 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 (see appropriate section for further detail).

A. Training

All the members of the UNCW IRB must complete the CITI online training course for IRB members prior to conducting IRB business. Members should also familiarize themselves with the Belmont Report and the UNCW IRB Assurance.

B. Protocol Review

1. Review new research projects that involve human subjects being conducted by UNCW faculty, staff, or graduate students or researchers from other institutions who are using UNCW faculty, staff or students as subjects.

   a. Undergraduate research that will not be published does not meet the definition of research with human subjects and does not require IRB
review unless it is conducted off-campus. However, this research must be reviewed by the advising/responsible faculty member.

b. Research using public, anonymous online sources, such as chat rooms, blogs or discussion boards, is not subject to IRB review as long as the online source has no terms in its privacy policy that assure confidentiality. However, the IRB strongly recommends that the researcher should post a notice in the online source stating that all comments will be reviewed for research purposes, and giving participants an opportunity to exclude their comments from the research.

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

2. Annually review previously approved research using human subjects.

   a. Continuing review of all approved research must be conducted no less than once per year. The exact time period for continuing review will be based on the degree of risk of the research.

   b. Continuing review will be substantive and meaningful.

C. Informed Consent

The IRB must ensure that the process for obtaining and forms for documenting informed consent is in accordance with the Code of Federal Regulations.

D. PI Notification

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

1. The UNCW IRB will consider the following factors when reviewing research with human subjects:

   a. a comparison of the foreseeable risks and the expected benefits of the research
   b. the experimental design
   c. the qualifications of the PI
   d. the method of subject selection
   e. inclusion and exclusion criteria
   f. the method of recruitment
   g. the process for obtaining and documenting informed consent
   h. the need for parental permission
   i. the process of obtaining and documenting the assent of minors
   j. the ways in which the privacy and confidentiality of subjects will be protected
   k. any special protections required for vulnerable populations

2. IRB members should utilize the “UNCW IRB Protocol Review Checklist” when reviewing research.

3. When the convened IRB approves research involving pregnant women, human fetuses, or neonates, prisoners, and children, all required findings must be fully documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding.

F. Meeting Procedures

1. The UNCW IRB will have a standing meeting once each month during the academic year to consider new and continuing research planned for that semester that requires full IRB review. The dates of these standing meetings
will be announced on the IRB website (http://www.uncw.edu/orssp/conduct-human.html).

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

3. 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, including at least one member whose primary concerns are in nonscientific areas (i.e., a quorum), 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.

G. Retention of IRB Records

1. General Responsibilities

   a. The IRB is also responsible for keeping adequate records of its members, research review procedures, minutes of IRB meetings, correspondence with researchers, and review of research.

   b. IRB records must be retained for at least 3 years, and records relating to research that is conducted must be retained for at least 3 years after completion of the research.

   c. The RCO in ORSSP and the IRB chair are the custodians of the records and shall retain them.

   d. Files must be accessible for inspection and copying by authorized representatives of the university and the DHHS, and by the public to
the extent allowed under NC state 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.

H. Registering IRB & Updating Assurance

The UNCW IRB, through ORSSP, must register with the Office of Human Research Protections, and update and renew UNCW’s Federal Wide Assurance with the Department of Health and Human Services.

VI. RESEARCHER RESPONSIBILITIES

Researchers are responsible for designing and implementing ethical human subject research, consistent with the three Principals 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 procedures, and IRB decisions, conditions, and requirements. Researchers are responsible for being properly trained, preparing timely research protocols and implementing them as approved, retaining research records, and reporting to the IRB (see appropriate section for further detail). Researchers should refer to the relevant IRB policies which follow.
A. Training

1. General Requirements

All persons (faculty, staff or students) involved in the design and/or conduct of research projects involving human subjects must receive the training described below or other form of training as approved by the RCO or IRB chair, regardless of the source of funding, if any, and category of the research. Examples of persons involved in the design and conduct of research projects include persons engaged in planning the study, writing survey questions, administering surveys, questionnaires or focus groups, and analyzing data. In particular, all individuals who obtain informed consent from research participants must have completed the required training. If there is any question about whether a particular activity involves research with human subjects, the researcher should review the Decision Charts available on the IRB website (http://www.uncw.edu/orssp/conduct-human.html), consult with the IRB chair, or contact the RCO in ORSSP.

2. Training Website

The Collaborative Institutional Training Initiative (CITI) online course is the approved training source. It is designed to demonstrate the highest ethical standards and to comply with all laws and regulations. The website can be found at http://www.citiprogram.org/. Other forms of training must be approved on a case-by-case basis by the RCO or IRB chair.

3. Certification of Training

Each person subject to the educational requirements must submit documentation of completion to the RCO. ORSSP will maintain a record of all training documentation received. ORSSP will not forward a Human Subjects Protocol Form to the IRB chair for review until all relevant documentation has been received.
B. Submission of Forms to the IRB

1. PIs are responsible for ensuring that all of their research activities involving human subjects are submitted to and approved by the IRB using the forms available on the IRB website (http://www.uncw.edu/orssp/conduct-human.html). PIs from other institutions may submit their institutional forms if they have already obtained IRB approval from their home institution and the form required by the home institution provides substantially the same information as the UNCW form. PIs from other institutions must receive UNCW IRB approval before starting any activities using UNCW populations or facilities.

2. PIs must submit the most current Human Subjects Protocol Forms and Annual Protocol Review Forms, along with all required attachments, at least two weeks prior to the IRB meeting when review by the full committee is required. When researchers anticipate exempt or expedited review, ORSSP must receive the signed hard copy of the applicable form and any supporting documentation at least ten days prior to the researcher’s desired start date to allow adequate time for IRB processing, review and approval.

3. PIs must designate on the protocol form the name of an alternate contact who would have the authority to report to the IRB in the researcher’s absence.

4. Amendments to approved protocols must be submitted and approved prior to implementation of any changes using the forms from ORSSP.

5. PIs should refer to their protocols by number in all communication with the IRB and ORSSP.

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

D. Reporting

1. Continuing Review

The PI is responsible for reporting the progress of approved research to the IRB, as often as and in the manner prescribed by the IRB, but no less than once per year, using the Annual Renewal form available on the IRB website (http://www.uncw.edu/orssp/conduct-human.html).

2. Adverse Events and Unanticipated Problems

   a. The PI or responsible person must report to the IRB any injuries, adverse events, or other unanticipated problems involving risks to subjects or others as described in the “Reporting Adverse Events” section of this policy.

   b. The PI or responsible person must inform the IRB of any problems with implementing the approved research procedures.

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 5 business days of notification.

4. Protocol Closure

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

E. Informed Consent and Assent/Permission Process

1. General Requirements
a. UNCW recognizes that informed consent is a process, not a form. Researchers must give subjects complete information about the research project, allow them to ask questions, and make sure they understand the information provided to them. Researchers must also inform subjects if there are any changes or new information available that may alter the subject's willingness to participate in the project.

b. Researchers must obtain and document informed consent and assent/permission in accordance with federal regulations, section VIII of this policy, and as approved by the IRB.

c. Researchers must use the UNCW IRB templates or informed consent checklist to prepare informed consent and assent/permission documents.

d. Informed consent documents and assent forms must be written in a manner that is understandable to the subject based on age, education level, developmental level and maturity.

2. Informed Consent Procedures

Researchers must use the original, stamped and approved consent form to make copies to be used in obtaining consent or assent/permission. Researchers must keep the signed copy of the informed consent form and provide an unsigned copy to each subject at the time of consent, unless the IRB specifically waives this requirement.

3. Informed Consent in Languages other than English

If a researcher will be using an informed consent document written in a language other than English, the researcher must submit to the IRB copies of the document in the foreign language along with an English translation.

F. 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 HHS at reasonable times and in a reasonable manner.

VII. CATEGORIES OF RESEARCH REVIEW AT UNCW

Only the IRB chair or designate can determine the category of research. Researchers cannot assume any research activities with human subjects do not require IRB review (see V.B.1.a for exception). Prior to determining the category of research, the IRB chair or designate 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 designate determines whether a research protocol falls under the exempt review category or requires expedited or full review. If the protocol is to receive expedited review, the IRB chair or designate will conduct the review, in consultation with one or more experienced IRB members, as needed. The IRB chair may consult with a computer expert regarding web-based data collection. Based on the Code of Federal Regulations Title 45 Part 46, the UNCW IRB will use the following categories of review in evaluating research protocols:

A. Exempt Review

Research in the category of exempt review may include normal educational practices, educational tests, surveys, interviews, or observation of public behavior when the subjects cannot be identified and the information gathered will not place the subjects at risk, research using existing data, documents, and records if publicly available and the subjects cannot be identified, and the evaluation of public benefit
service programs. Exempt approval means that the study is also exempt from continuing review.

B. Expedited Review

1. General Considerations for Expedited Review

Expedited review covers research that poses no more than minimal risk to human subjects. “Minimal risk” is the risk encountered in everyday life. Expedited review may be employed for minor changes in previously approved research, collection of small blood samples, collection of data through non-invasive procedures routinely employed in clinical practice, collection of data from voice, video, digital, or image recordings, the use of materials that have been collected solely for non-research purposes, research on individual or group characteristics or behavior, or research employing survey, interview, or oral history methodologies.

2. Expedited review may be used for these types of research regardless of the age of the subjects.

3. 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 review by the full IRB.

4. All IRB members will be informed of research approved under expedited review.

C. Full Review

Research that does not meet the criteria for exempt or expedited review must receive full review. This includes:
1. Research where the subjects can be identified and the data collected poses risks to the subjects, in terms of their financial or social standing, employment, or criminal or civil liability;

2. Research that involves more than moderate exercise;

3. Research on individual or group characteristics or behavior that employs deception of the subjects or where they are placed under psychological or emotional stress;

4. Research that poses potential physical, psychological, social, legal, or other risks to the subjects.

D. Special Consideration for Vulnerable Populations

1. Research at UNCW on vulnerable populations, such as minors under age 18, prisoners, pregnant women, seriously ill patients, and mentally incapacitated adults, will receive careful consideration to be certain that there are adequate procedures in place to protect these vulnerable subjects.

2. All research involving prisoners must include a review of the Prisoner Participant Form that should be submitted at the time of initial review. 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 category of 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 mentally incapacitated adults will require special attention regarding both surrogate consent and participant assent.
VIII. INFORMED CONSENT PROCESS

A. General Process

Researchers must use one of the approved Informed Consent Form Templates and/or one of the approved Assent/Permission Form Templates, or the Informed Consent Checklist to prepare informed consent or assent/permission documents for IRB review. The templates and checklist are available from ORSSP or on the IRB website (http://www.un cw.edu/orssp/conduct-human-forms.html). Approved informed consent documents are stamped, initialed and dated with an expiration date. Researchers must use the approved document when obtaining consent. Researchers must give a copy of the approved consent form to each participant for his/her records.

B. Research Involving Minors

1. Definitions specific to this section

   a. Minor – North Carolina law defines a minor as a person under age 18

   b. Assent – A child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (45 CFR §46.402).

2. Assent/Permission Requirements

   a. Permission from Parent or Guardian

       A parent or guardian must give permission for a minor to participate in research unless in rare circumstances this requirement is specifically waived by the IRB in accordance with 45 CFR §46.408(c). The IRB has the authority to require researchers to obtain permission from both parents of a subject if the situation warrants this approach.

   b. Assent from Minors
Minors must assent to participate in the research beginning at age 5 unless the IRB finds the subjects are unable to do so due to a disability or other factor. When minors are younger than age 5, researchers may request on the protocol form an alteration of the standard process as described below to seek permission from a parent/guardian without obtaining assent from minors.

c. Documentation of Assent/Permission

The standard assent/permission process is to provide parents/guardians with a permission form and minors with an assent form. Researchers may use a combined assent/permission form with two signature sections or use two separate forms. Researchers must justify deviations from the standard process on the protocol form.

d. Assent Variations Due to Age of Subject

Obtaining assent and documenting assent are two separate processes. When minors age 5-6 are involved in the research, the IRB views verbal agreement as sufficient. Researchers must request an alteration of the standard process for documenting assent and must submit the assent script that will be read to subjects to the IRB for approval. When minors age 7 and over are involved in the research, researchers must follow the standard process unless this requirement is specifically waived by the IRB. Assent forms or assent sections on permission forms must be written in language appropriate to the age and maturity of the subjects.

C. Criteria for waiving or altering the informed consent requirements

1. The IRB may consider requests to alter the standard consent process in accordance with 45 CFR 46.116(c), 46.116(d), and 46.408(a), (b) and (c).
1. The IRB chair may approve waivers or alterations to consent forms for research projects reviewed under expedited review.

2. Anonymous Surveys

The UNCW IRB does not require written consent for completely anonymous surveys and questionnaires that do not require the subjects to react or respond to scenarios, photographs or information other than the survey or questionnaire itself. However, the PI must include the following statement or something similar at the beginning of the survey or questionnaire: “Your participation in this research study is entirely voluntary. You may refuse to participate or you may stop participating at any time without penalty or loss of benefits.”

3. Online Surveys

The UNCW IRB does not require written consent when anonymous online surveys are conducted provided the PI follows the requirements of #5 above. In addition to those requirements, the PI must notify subjects that while their responses will be kept secure when they are in the PI’s possession, the PI cannot guarantee security during transmission of data due to keylogging and spyware technology that may exist on any computer used by the subject to respond to the survey.

D. Recruitment and Remuneration

1. The IRB chair will review all recruitment materials and remuneration for expedited reviews.

2. The IRB members will consider these aspects of the research protocol for full review.

3. Recruitment materials must be reviewed by the IRB chair or the full IRB.
4. 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.

5. Remuneration should be reasonable in relation to the specific population.

6. Remuneration should not be so great to be considered a “coercive offer”.

7. Remuneration must be fully described on the consent or assent/permission form.

IX. RESEARCH PROTOCOL EVALUATION PROCEDURES

All of the forms referred to in the IRB procedures may be obtained from ORSSP or on the IRB website (http://www.uncw.edu/orssp/conduct-human-forms.html).

A. Submission requirements

To begin the review process, the PI must submit one signed hard copy and one electronic copy of the following to the RCO in ORSSP:

1. Human Subjects Protocol Form,

2. Proposed Consent Form, and/or Assent/Permission Form,

3. Any relevant grant applications,

4. Recruitment materials, and

5. All relevant attachments from PART N of the Human Subjects Protocol Form.

B. Incomplete Submissions
The chair or designate will notify PIs of incomplete protocols. If the protocol remains incomplete after 30 days from notification, it will be removed from review.

C. Review Procedures

1. Type of Review Needed

The IRB chair or designate will evaluate the protocol as (1) exempt from further review, (2) eligible for expedited review, or (3) requiring full review, based on the Code of Federal Regulations, Title 45 Part 46.

2. Procedures for Exempt Review

The IRB chair or designate is authorized to review and approve protocols that are exempt from further IRB review.

3. Procedures for Expedited Review

   a. The IRB chair or designate is authorized to approve or require modifications to protocols qualifying for expedited review. If the reviewer has questions concerning a protocol, he or she will consult with other members of the IRB to determine whether or not full review may be needed.

   b. The expedited reviewer may approve a research protocol. However, full review is required for disapproval.

   c. All members of the IRB will be notified electronically of all protocols approved by expedited review and will be able to review the relevant protocol forms upon request.

4. Procedures for Full Review
a. The PI will be asked to submit the appropriate documentation to the RCO in ORSSP at least two weeks before the scheduled IRB meeting.

b. The RCO will distribute these forms electronically to all IRB members at least one week prior to the IRB meeting.

c. A majority of the IRB members (including at least one non-scientist) must be present at the meeting for a full review of any protocol to take place.

d. The PI may be invited to present the research protocol and answer questions at this meeting.

e. The protocol must be approved by a majority of the IRB members present.

f. IRB members who are also researchers on projects under review may not participate in the discussion of or the vote on their own research and may not be present when these take place.

g. IRB members may not be present in the meeting room when the IRB reviews research in which they have a conflicting interest, and such should be noted in the IRB meeting minutes.

h. 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 non-scientist member), the IRB may not take further actions or votes unless the quorum can be restored.

i. Members of the IRB who vote to disapprove a protocol shall submit their reasons in writing to the IRB chair within 7 days of the meeting.

D. Review Results

Following IRB review the PI will be notified in writing as soon as possible of the results of the review.
1. Protocol Approval

   a. If the protocol is approved, the IRB chair will send the PI and ORSSP a copy of the signed first page of the Human Subjects Protocol Form, which also specifies the type of review conducted.

   b. All IRB approvals are effective for one year.

2. Modifications and Clarifications

   a. 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 HHS regulations at 45 CFR 46.111, IRB approval of the proposed research should be deferred, pending subsequent review by the convened IRB of responsive material.

   b. When the convened IRB stipulates specific revisions requiring simple concurrence 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.

   c. When IRB approval is contingent upon modifications to the research procedures or the informed consent process or form, the PI will be contacted and informed 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 chair.

   d. 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 Human Subjects Protocol Form will be
signed, a copy of the first page will be returned to the PI, and a copy will be sent to ORSSP. The IRB chair will also forward the modifications to ORSSP.

3. Protocol Disapproval

If the protocol is disapproved the PI will be notified in writing of the reason(s). The PI will also be given 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.

E. Continuing Review (Annual Renewal)

1. Continuing review will be substantive and meaningful.

2. Research that continues more than one year past its original approval date must be re-approved. The Consent Form or the Assent/Permission Form must also be re-approved.

3. For continuing review, one signed hard copy and one electronic copy of the following should be sent to the RCO in ORSSP:

a. The Annual Protocol Renewal Form,

b. If applicable, the Consent Form and/or Assent/Permission Form to be stamped, and

c. All other relevant attachments from PART I of the Annual Protocol Renewal Form.

4. More Frequent Review
The IRB may determine that some protocols require continuing review more often than annually. This may be based on risks to participants or the results of an IRB audit.

5. Type of Review

a. If the protocol was originally exempt or approved through expedited review, the IRB chair or designate may approve the continuation of the research.

b. If the protocol was originally approved by full review, the full IRB must consider and vote to approve continuation unless data collection is complete and the activities are limited to data analysis. The forms will be distributed to the IRB members one week prior to the IRB meeting. The same review procedures apply for continuing review as are used in full review.

6. Approval of Continuing Review

If the protocol is approved for continuation, the Annual Protocol Renewal Form will be signed, a copy of the first page will be returned to the PI, and the original will be sent to ORSSP. The IRB chair will stamp the Consent Form and/or the Assent/Permission Form. The dates of approval and expiration of the research will be noted on the stamp, with the IRB chair’s initials. The original consent form will then be returned to the PI. Copies of this stamped document must be used in obtaining consent or assent and permission. A copy of the stamped form will be filed with the Human Subjects Protocol Form in the IRB chair’s office and in ORSSP.

F. Review of Protocol Amendments

All proposed amendments 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 and approved by the IRB prior to their implementation.
1. Submission Requirements

One signed hard copy and one electronic copy of the following should be sent to the RCO at ORSSP:

a. The Protocol Amendment Form,

b. If applicable, the proposed Consent Form and/or Assent/Permission Form, and

c. All relevant attachments from PART H of the Protocol Amendment Form.

2. Extent of Changes

The IRB chair or designate will determine whether the amendments involve major or minor changes.

a. Major Changes

Examples of major changes are the addition of vulnerable populations or a change from anonymous to confidential collection of information. If the changes are major, they may require full review and an IRB meeting may be called. If full review is required the same procedures outlined in IX.C.4 will be followed.

b. Minor Changes

Examples of minor changes include an additional survey instrument, a change of location, or additional participants of the same non-vulnerable population. If the changes are minor, they may be approved by the IRB chair or designate.

3. If the amendment is approved, the first page of the Protocol Amendment Form will be signed. One copy of the signed first page will be returned to the PI, and one the original will be returned to ORSSP. If there are changes
that require a new Consent Form or Assent/Permission Form, the new form will be stamped by the IRB chair. The dates of approval and expiration of the research will be noted on the stamp, with the IRB chair’s initials. The new form will then be returned to the PI. Copies of this stamped document must be used in obtaining consent or assent and permission. A copy of the stamped form will be filed with the Protocol Amendment Form in the IRB chair’s office and in ORSSP.

4. The PI must securely attach all approved amendments to the front of the original protocol document in his or her file.

G. Protocol Closure

All expedited and full review protocols must request protocol termination. This practice ensures that the IRB and ORSSP are aware of all research activities and any problems that were encountered, and documents that the research has ended and no more renewals are necessary. One signed hard copy and one electronic copy of the Protocol Closure Form must be sent to the RCO at ORSSP.

X. 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. UNCW is not a “covered entity” under HIPAA, and thus is not required to comply with HIPAA. 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 policy applies where UNCW researchers are receiving PHI from HIPAA covered entities. The HIPAA Privacy Rules govern 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.

C. De-identified PHI

De-identified PHI is not subject to the HIPAA privacy regulations. 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 require the removal of over eighteen criteria. 45 CFR §164.514. The covered entity which 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 researcher is strongly recommended to review the HIPAA resources available on the UNCW IRB website (http://www.uncw.edu/orssp/conduct-human-materials.html). A researcher may be required by the disclosing covered entity to receive 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: either that

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.

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 if 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.

XI. REPORTING ADVERSE EVENTS

A. General Requirements

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 below to the IRB by the PI or, in the absence of the PI, the responsible person designated on the protocol.

B. Definition of Adverse Event

Any untoward or unfavorable occurrence in a human subject, physical or psychological, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.

C. Serious Injury or Problem
In the event of a very serious problem, such as a serious injury to a subject, the PI or responsible person must call the IRB chair as soon as feasible after the occurrence of the problem.

1. If the PI or responsible person is unable to reach the IRB chair, the PI or responsible person must call the RCO.

2. Within 5 days of the problem, the PI or responsible person must also submit an Adverse Event Report.

D. Less Serious Problem

In the event of a less serious problem, the PI or responsible person must submit an Adverse Event Report to the RCO in ORSSP within 5 days of the occurrence of the problem. The RCO will forward the document to the IRB chair. The IRB chair will determine the significance of the adverse event.

E. Adverse Event Procedures

1. Minor Event

If the event is determined to be minor, the IRB chair and the RCO will place the Adverse Event Report in the appropriate file.

2. Major Event

If the event is determined to be major, the IRB chair will promptly inform the IO in writing within 15 days of the event (however, personal communication such as phone or e-mail should occur prior to this date, based on the level of risk involved). The RCO will promptly inform the full IRB. If the research is funded, the RCO will promptly inform the Director of Sponsored Programs, who will either notify the sponsor or direct the RCO to notify the sponsor. The RCO is responsible for reporting the event to the relevant regulatory agencies, and OHRP (in writing within
20 days of the event, but personal communication should occur prior to this date) and for documenting this reporting.

F. 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.

G. Investigation of Research Project

The IRB chair, IO, ORSSP, or full IRB may request an investigation of a research project. ORSSP, in conjunction with the IRB chair, will investigate the research project and submit a report to the IRB within 2 weeks.

XII. 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.

B. Summary of University Policy

The University Policy on Conflicts of Interest and Commitment (Faculty Handbook, VII.C.8) specifically includes research activities in its definition and examples of “conflict of interest.” According to university policy, each faculty member and EPA non-faculty employee 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 faculty member or non-
faculty employee's supervisor.

C. IRB Evaluation of Conflicts of Interest

The UNCW IRB also requires information relating to potential conflicts of interest and
the appearance of conflicts of interest for all members of the research team.

1. The IRB chair will make this determination based on the information provided
in the IRB protocol forms.

2. The PI must provide the following information concerning financial interests:
   a. any financial relationships held by the PI, or any other individuals or
      institutions involved in the research, which could create perceived or
      actual conflicts of interest and
   b. any compensation received by the PI, or any individuals or institutions
      involved in the research, that may be affected by the study outcome.

3. The IRB chair will evaluate the financial interest information provided on the
   protocol forms to determine whether or not there is a potential conflict of
   interest or the appearance of a conflict of interest for the PI or any individual
   or institution involved in the research.

4. If the IRB chair finds evidence of such a conflict or the appearance of such a conflict,
   the full IRB will discuss this with the PI during full review of the protocol.

5. In its deliberations on conflicts of interest, the IRB will adhere to the
   University Policy on Conflicts of Interest and Commitment section,
   “Management of Conflicting Interests.” The designated official(s) must review
   all financial disclosures and determine whether a conflict of interest exists and,
   if so, determine what actions should be taken by the university to manage,
   reduce or eliminate such conflict of interest. A conflict of interest exists when
   the designated official(s) reasonably determines that a Significant Financial
Interest could directly and significantly affect the design, conduct, or reporting of the results of the work. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

a. Public disclosure of significant financial interests;

b. Monitoring of research by independent reviewers;

c. Modification of the research plan;

d. Disqualification from participation in all or a portion of the research;

e. Divestiture of significant financial interests; or

f. Severance of relationships that create actual or potential conflicts.

XIII. AUDIT PROCEDURES

A. Audit of Research Project

1. The full IRB or the IRB chair may request an audit of any study that has been approved by the IRB.

2. ORSSP, Internal Audit or the Chancellor can also initiate an audit randomly, as part of an investigation, or for any other reason.

3. The RCO will conduct ORSSP audits along with one IRB member.

4. The PI is expected to cooperate fully with the IRB and ORSSP.

B. IRB and ORSSP Audit Report
1. Following audit a written report will be generated and sent to the PI, copies of which will be submitted to the IRB chair and filed in ORSSP.

2. The IRB chair will determine if there are any serious acts of noncompliance or activities that may jeopardize the welfare of human subjects or others.

3. Major noncompliance will be reported promptly to the IO and forwarded to the full IRB for review.

4. The PI will be asked to respond to any infractions cited in the report within a specified time period.

5. If at any time an auditor finds a serious noncompliance or practice that may jeopardize the welfare of human subjects or others, the auditor may contact the IRB chair prior to generating a formal report.

6. ORSSP will coordinate the notification of outside agencies based on federal regulations and the policies of the funding agency.

C. Unreported Changes to Research

The IRB can use the following to determine which projects need verification from sources other than the PI that no material changes have occurred since previous IRB review. Such criteria includes the following:

1. randomly selected projects,

2. complex projects involving unusual levels or types of risk to subjects,

3. projects conducted by PIs who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB, and
4. projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

XIV. NONCOMPLIANCE WITH IRB POLICIES

A. Unapproved Research

1. Research conducted without IRB approval must stop until IRB approval is obtained.

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

B. Findings of Noncompliance

1. 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 if the violation is minor or major.

   a. Minor Noncompliance

      If the noncompliance is deemed to be minor, and it is the first noncompliance by a PI or research team member, the IRB chair will send a notification of the minor noncompliance to the PI, researcher (if different from the PI) and the IRB. A copy of the notification will be filed in ORSSP.

      i. The researcher and/or PI will be asked to respond within a specified time period, and to correct the noncompliance.

      ii. The IRB chair and/or ORSSP will promptly conduct a review of the response and of the corrective action taken.

      iii. Upon finding that the researcher is within compliance, a report will be filed in ORSSP and the IRB will be notified.
iv. If the review finds that the researcher is still not in compliance, the department chair or other immediate supervisor of the researcher will be notified and the PI and researcher (if different from the PI) will be instructed to stop the research.

v. The researcher and/or PI will be instructed to submit a plan to correct the noncompliance to the RCO in ORSSP.

vi. The RCO will forward the plan to the IRB chair and department chair or other immediate supervisor of the researcher for review.

vii. Upon acceptance of the plan, the IRB chair will notify the PI that s/he may resume the research. If the same researcher is subsequently found to be in noncompliance for the same offense, the IO and IRB will be notified and the IRB will convene to determine appropriate disciplinary action.

b. Major Noncompliance

If a noncompliance is deemed to be major, or if a significant number or repeated minor infractions are found, such activities will be reported promptly to the IO and forwarded to the full IRB for action. The IRB can vote to:

i. Take no action

When the IRB votes to take no action, the PI and researcher (if different from the PI), his/her immediate supervisor, and the IO will be notified in writing and a report will be filed in ORSSP.

ii. Open an in-depth investigation

When the IRB votes to open an in-depth investigation, ORSSP will conduct an audit and coordinate an investigation.
iii. Suspend the protocol

When the IRB votes to suspend the protocol, the PI, his/her immediate supervisor, and the IO will be notified in writing of the date the suspension must commence. When a protocol is suspended, no new subjects can be recruited or enrolled into the study, and all enrolled subjects must be phased out of the project. The PI may be asked to provide the IRB with a plan to phase out subjects, which must be accepted by the IRB, and must contact the IRB when all subjects have been phased out. The study may resume only when the IRB votes to lift the suspension of the protocol.

iv. Terminate the protocol

When the IRB votes to terminate the protocol, the PI and researcher team member (if different from the PI), his/her immediate supervisor, and the IO will be notified in writing of the date the termination must commence. When a protocol is terminated, all research activities related to this protocol must cease. The IRB may direct the PI as to how to terminate the protocol. Typically, no new subjects can be recruited or enrolled into the study, all enrolled subjects must be notified of the termination of the project, and all data collection, analysis and dissemination must cease. The IRB may vote to lift the termination of the protocol or allow some parts of the study to continue.

v. Prevent the researcher/PI from conducting research at UNCW

In extreme cases, the IRB may decide to no longer permit a researcher to conduct research at UNCW. When the IRB votes to prevent a researcher from conducting research, the PI and research team member (if different from the PI), his/her immediate supervisor, and the IO will be notified in writing. When the IRB votes to prevent a researcher from conducting research at UNCW, all relevant research activities must cease.
2. In addition to or in lieu of the above-mentioned actions, the IRB can vote to require the researcher to complete additional training in the protection of human subjects, require more frequent than annual review of protocols, place a researcher on probation, or take any similar disciplinary action appropriate to the magnitude of the noncompliance.

3. The IRB, IO or Chancellor may take any of the above actions when it is determined a research protocol is not being conducted according to federal or local regulations or UNCW policies and procedures, has deviated from its approved protocol, or raises concerns about the risks to human subjects.

C. Notification of Agencies

ORSSP will coordinate the notification of outside agencies based on federal regulations and the policies of the funding agency.

D. Appeals

The researcher/PI may appeal any action by the IRB in writing to the IRB chair within 10 business days. The IRB’s decision will stand until the appeal can be properly evaluated.

XV. 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 ORSSP. Complaints should be directed to the chair of the IRB, Dr. Candace Gauthier, in the Department of Philosophy and Religion (910-962-3558), or to the RCO, Leanne Prete, in ORSSP (910-962-7774). Complaints may be filed anonymously. All complaints will be thoroughly investigated by the IRB.
and ORSSP or as appropriate, referred to the Dean of the Graduate School and Research for investigation under the university’s Research Misconduct Policy.