Committee on the Oversight of the Faculty Handbook
Meeting Agenda
Thursday, October 24, 2019 at 3:30
Location: UC Annex 217

Committee Members:

Jennifer Wells (CHS)
Xinyan Shi (SBS)
Olivia Oxendine (EDUC)
Roger Ladd (LETT)
Thomas Dooling (NSM)
Vacant (ARTS)
Rachel B. Smith (FERS Chair)

I. Call to Order
III. Approval of Agenda
IV. Review of Charge (Appendix A)
IV. Election of Chair
IV. Election of Secretary
V. Old Business
VI. New Business
    a. Request from IRB (Appendix B)
    b. General Scope/Focus and Approach
        a. Review for Outdated Systems/Policies (e.g. language about evaluations talked about passing out in the classroom, which obviously can't be applied to online classes [FERS is handling])
        b. Review alignment with forms (e.g, the handbook says "A student may withdraw from a course after the drop-add period but prior to and including the last day of the first week of classes after midterm grades are reported, with a grade of W, if the student obtains the signature of her or his advisor." The form requires the instructor's signature [EMS is handling])
        c. One section/year?
        d. Big picture things: i.e. gender-neutral language
VII. Announcements

Upcoming Meetings:

Thursday, November 21, 2019	3:30 PM	217 UC Annex
Thursday, January 16, 2020	3:30 PM	217 UC Annex
Thursday, February 20, 2020	3:30 PM	217 UC Annex
Thursday, March 19, 2020	3:30 PM	217 UC Annex

VIII. Adjournment

The Committee for Oversight of the Faculty Handbook shall consist of seven members: the Chair of the Faculty Evaluation Review Subcommittee, who serves in an ex officio capacity, and one member elected from each Division of the General Faculty in General Faculty-wide elections conducted by the Committee on Committees & Elections. Any member of the General Faculty with tenure and the rank of Associate or Full Professor is eligible for election. Membership is for three-year staggered terms, and the chair and secretary of the Committee shall be appointed by the Faculty Senate Chair from its Divisional membership.

The Committee, through its continuous review and oversight of the Faculty Handbook, shall assure the accuracy and currency of the Faculty Handbook and maintain the document and its previous versions in a digital format accessible via the Faculty Senate's official website. The committee shall implement the acts of the Senate in the Faculty Handbook and, as necessary, edit and/or update the Faculty Handbook for consistency, accuracy, and currency. The Committee must present any such alterations to the Faculty Handbook to the Faculty Senate; with subsequent action undertaken at the pleasure of the Faculty Senate.

Appendix B: Request from IRB for changes

Note from Erik Tracy, IRB Chair: The OLD document is the old IRB section in the faculty handbook. The NEW document is the revised IRB section that was voted on and passed by the IRB. I have underlined the new revised areas, so that the committee can compare the new and old sections.

Also, the IRB is constrained by federal guidelines; there are certain areas and items that the IRB must adhere to based on federal guidelines. Thus, there are some areas of the revised section that cannot be changed. For instance, a member of the Faculty Handbook committee might want a certain section revised, but according to federal guidelines, this section might not be able to be revised. If need be, I can speak to the committee about these areas if they find problems with the revised document.

REVISED VERSION

Institutional Review Board for Research with Human Subjects (IRB)
Purpose and Scope of IRB Approval

The Institutional Review Board is required by federal law to review and approve ALL research proposals that involve human subjects; that is, any research involving people including adults, children and infants. Special protections are accorded to minors, pregnant women and fetuses, institutionalized populations, the mentally disabled, and economically and educationally disadvantaged persons.

The federal regulations define research as a systematic investigation, including testing and evaluation, designed to develop or contribute to generalized knowledge. A human subject is defined as a living individual about whom an investigator conducting research obtains personal data through intervention or interaction with the individual or identifiable private information.

Federal law requires that all research protocols involving human subjects must be reviewed and approved by an IRB, even if the proposal is not externally funded. The UNC Pembroke IRB must review any human subjects research conducted at UNC Pembroke regardless of outside approval. This includes all research with human subjects conducted at UNC Pembroke including faculty, staff and/or students as research subjects or by UNC Pembroke faculty, staff and or students at any location. Research conducted as part of a classroom exercise or a course assignment MAY be exempt from IRB review. However, the IRB Chair or designate must make that decision based upon a protocol review.

The Institutional Review board at UNC Pembroke ensures that all research that is undertaken protects participants from unreasonable risks to their health, general well-being or privacy. Specifically, the University is concerned that all research and related activities involving the use of human subjects:

1. Protect the rights and welfare of persons participating as subjects, including, but not limited to the protection of identifiable private information.
2. Use as subjects only persons who have freely given informed consent (or in the case of minors, consent from the parent or legal guardian and assent from the minor) after being made aware of the potential risks and/or benefits of a particular research project, and
3. Allows participants advance knowledge of potential risks of participation and knowledge that these risks have been evaluated by an IRB.

Review and approval of all research protocols is the responsibility of the Institutional Review Board (IRB), a panel of UNC Pembroke faculty, administrators and a community representative. The IRB is responsible for protection of the rights, welfare and privacy of research subjects through an initial review and subsequent oversight of all human subjects research.

Under both federal and university policy, the IRB has the authority to approve proposed research, to require revisions in proposed research to ensure it includes safeguards to protect subjects, or to refuse to approve proposed research if the applicant cannot or will not revise the protocol to prevent identified risks to the subjects. Once the research is approved the IRB has the authority to monitor the research to ensure that research is conducted as approved. Additionally, multi-year research projects are required to be reviewed and re-authorized according to the review process outlined below.

All IRB reviews begin with an application (see application procedures below). Following an initial review of the application describing the nature of the research, a proposal may be:

- *Exempt* from further IRB review
- Appropriate for an *expedited review* by the chairperson of the IRB or another IRB member, or members, as designated by the chair.
- Subject to *full review* by the *full* IRB

Only the IRB Chair, or designee, can determine which type of review is applicable. Regardless of level of review, a record must be kept by the IRB of all research involving human subjects at UNC Pembroke. It is the goal of the UNC Pembroke IRB to support the development of protocols that protect human subjects and support research. Researchers with protocols that lack protection for human subjects will be offered guidance to make necessary modifications to augment approval. No proposal will be rejected without recommendations for modification and resubmission.

Further policy and procedure information, forms to be used for proposals, and links to other useful sites are available on the IRB web site at http://www.uncp.edu/irb. The current IRB Chair can be contacted by email at irb@uncp.edu.

UNC Pembroke Institutional Review Board (IRB) Policies and Procedures

IRB Membership

The Provost and Vice Chancellor for Academic Affairs appoints IRB members for Academic Affairs for three-year terms. The Institutional Review Board includes at least five faculty members, and it falls under the administrative oversight of the Office of Sponsored Research Programs (OSRP). The members should reflect the diversity of the institution and the community. A minimum of two members should be experienced in human subjects research. There must be one non-scientist member and one member who are not affiliated with UNC Pembroke. A chair is elected at the first meeting of each academic year. Names of current IRB members and their email addresses are located on the IRB website http://www.uncp.edu/irb

No IRB member may participate in the review of a proposal in which the member has a conflict of interest. Specialists may be invited by the IRB to provide technical assistance, if the subject matter is deemed outside the expertise of the sitting IRB members.

Operating Procedures

The University IRB will review all research involving human subjects carried out at UNC Pembroke or by UNC Pembroke faculty, staff or students. The IRB is responsible for approving research protocols, requiring modifications, or disapproving research. The IRB is responsible for the development of all forms requesting review and guidelines for informed consent that reflect federal regulations. The IRB will notify researchers of their decisions by email. Additional written notification will be provided upon the request of the applicant.

The IRB will meet monthly during the academic year. For a protocol to be considered for review at the monthly meeting, it must be submitted by the 15th of the previous month; applications submitted after this deadline will be considered at the next monthly meeting. For example, if the IRB is meeting in February, then all applications received on or prior to January 15 will be considered at the February meeting; if an application is submitted on January 20, then it will be considered at the March meeting. If there are no protocols to review, the IRB will not meet for that month.

For a research protocol that requires a full board review, a majority of the membership must be present to consider any proposal and a majority vote is required for any Board action. For board meetings where a full board review of a protocol takes place, the principal investigator (or delegate) should attend to present a review of the research and answer any relevant questions posed by the committee.

The IRB will keep adequate records of all protocols and requests for continuing review, including decisions made. The minutes of each IRB meeting will include the names of members who attended, actions taken by the Board, the outcome of voting on research protocols including numbers of votes for and against, the rationale for requiring modifications to a protocol or informed consent process, and a summary of discussion of controversial issues and their resolution. Records of all protocols, requests for continuing review, and records of IRB reviews and meeting minutes will be kept on file for a minimum of three years.

IRB Proposal Submission and Review Procedures

An application for IRB review includes a completed IRB Protocol Application (available online at https://www.uncp.edu/academics/research/institutional-review-board/forms-and-guidelines) and all supporting materials. Supporting materials typically include all recruitment materials, consent forms, survey instruments, debriefing statements, data use agreements, and human subjects research training documentation (see 8-3.B.5). IRB applicants should submit one electronic copy of the application and all supporting materials to irb@uncp.edu. Additionally, one original signed copy of the application should be sent to the current IRB Chair via Campus Mail.

IRB review requests will be acknowledged by electronic mail within three business days of receipt. The IRB Chair or designee will evaluate the protocol and determine the required level of review and inform the Principal Investigator of this decision as soon as it can be determined. Based upon federal guidelines, the UNC Pembroke IRB will utilize the following categories of review:

Exempt from Review

Projects that are traditionally exempt from an expedited or full IRB review include normal educational practices, educational tests, surveys, instruments, or observation of public behavior when subjects cannot be identified and the information gathered will not put 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. Applications that are exempt from review will be notified by electronic mail as soon as that decision is made. 45 CFR § 46 has determined which categories of research are exempt from review (Protection of Human Subjects 2018).

Protocols that are developed for either instructional purposes or teaching research methodology and are not designed to contribute to generalized knowledge may be exempt from review. Under these circumstances the instructor assumes ethical and professional responsibility to monitor the progress of all research in the classroom. Research on vulnerable populations, including minors, pregnant women, fetuses, prisoners, seriously ill, and mentally incapacitated individuals may not be exempt from review. An Exempt Review determination does not imply that research subjects are exempt from human subjects protections.

Protocols that are approved as exempt from review are valid for three years. Researchers may request an extension beyond three years if necessary by contacting the IRB Chair and submitting an updated Protocol Application.

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 or interview methodologies. Expedited review may be used for these types of research regardless of the age of the subjects. The Secretary of HHS (Health and Human Services) will determine the list of research categories eligible for expedited review at least every eight years and amend it as needed (Protection of Human Subjects 2018).

Expedited reviews are completed by the chairperson of the IRB or another IRB member, or members, as designated by the chair.

The initial comments from the IRB for expedited reviews are generally completed within a timely manner. Modifications to the protocol may be requested by IRB members participating in the review during this review process. The applicant will be notified by electronic mail as soon as a decision is made.

Protocols that are approved through an expedited review are valid for three years. Federal guidelines allow each institution's IRB to determine the length that the expedited protocol is active. Furthermore, this time frame may change based on a vote of the IRB members. Researchers may request an extension beyond this time frame by contacting the IRB Chair and submitting an updated Protocol Application.

Full Review

Full IRB review includes 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. It also includes research that involves more than moderate exercise, research on individual or group characteristics or behavior that employs deception of the subjects or where they are placed under psychological or emotional stress, and research that poses potential physical, psychological, social, legal or other risks to the subjects. This list of example research studies is subject to change based on revised federal guidelines.

Research targeting vulnerable populations, including minors (unless an expedited review is allowed), pregnant women and fetuses, institutionalized populations, the mentally disabled, and economically and educationally disadvantaged persons will receive a full review to insure that adequate protections are in place.

A protocol that will be reviewed by the full board will be assigned to the next available board meeting on the schedule. In order for the full board to review the protocol, it must be submitted by the 15th of the prior month. For example, if a researcher submits a protocol on January 10, then it will be considered at the February meeting. If a researcher submits a protocol on January 20, then it will be considered at the March meeting. The research protocol will be distributed electronically to all board members prior to the meeting. A majority of board members must be present at the review meeting. The Principal Investigator will be invited to present the research protocol and answer questions at this meeting. The protocol must be approved by a majority of the members present. Members of the IRB who vote to disapprove a protocol shall submit their reasons in writing to the IRB Chair. Protocols that are approved through a full review are valid for one year. Researchers may request an extension beyond one year if necessary by contacting the IRB Chair and submitting an updated Protocol Application.

Changes to Existing Protocols, Adverse Events, and Renewal Procedures

Regardless of the level of review or existing approval, any changes made to the research protocol must be submitted to the IRB for review in writing prior to their implementation, as they may affect the status of a review. Additionally, the Principal Investigator is responsible for reporting any adverse or unanticipated events that may occur during their research to the IRB immediately, and no later than one week from their occurrence.

In order to submit changes to an existing protocol, Principal Investigators should add the proposed changes to their IRB Protocol Application and submit it electronically to the IRB Chair.

In order to apply for a renewal of an existing protocol, the Principal Investigator should notify the IRB no later than 30 days prior to the expiration of their approval. Renewal requests should include the submission of an electronic copy of the approved IRB Protocol Application with changes added to the file. In addition, any new recruitment materials, consent forms, or other supplementary materials should be submitted with the renewal application. It is the Principal Investigator's responsibility to keep an electronic copy of their approved IRB Protocol Application in order to facilitate the submission of changes and renewal requests.

According to the United States Department of Health and Human Services, a continuing review must take place at a convened meeting of the IRB in which a majority of the members are present and at least one member is a non-scientist. For the continued review to be approved, it must receive the support of a majority of the members that are present (45 CFR 46.108(b)). If there is not a quorum of members present during the meeting, then the IRB may not take any further action on the protocol. Action may only be taken on the protocol if a quorum of members is present (45 CFR 46.108(b)). Furthermore, during the IRB convened meeting, the minutes of the IRB meeting should have sufficient detail to demonstrate actions taken by the IRB. These actions may include, but are not limited to, votes on actions and a summary of the discussion relating to revisions of the protocol under review (45 CFR 46.115(a)(2)). If an IRB member needs to be recused because of a conflict of interest, then this recusal will also be reflected in the minutes.

It is the Principal Investigator's responsibility to keep an electronic copy of their approved IRB Protocol Application in order to facilitate the submission of changes and renewal requests.

Training on Human Subjects Research

To provide investigators with up-to-date information about the regulatory requirements for conducting research, the IRB requires that each researcher review core concepts for the responsible conduct of research with human subjects. In this instance, a researcher is defined as an individual that is listed on the research protocol, an individual that has contact with human participants, or an individual that has contact with human participants' identifiable data. Prior to an approval letter being issued, the researcher,

or researchers, will need to complete an OHRP approved training and submit documentation to the IRB Chair. The expiration date on the completed training certificate should extend the length of the research study. The IRB will provide a link to an approved web-based training module on the IRB website https://www.uncp.edu/academics/research/institutional-review-board/forms-and-guidelines).

Research Misconduct in Human Subjects Research

The IRB will promptly report any potential research misconduct involving human subjects by Principal Investigators affiliated with UNC Pembroke to the Provost and Vice Chancellor for Academic Affairs. The procedures for handling an allegation of research misconduct are defined in the section below on "Misconduct Related to Research."

Additionally, the IRB is required by federal law to promptly report certain incidents to the Office for Human Research Protections (OHRP), a division of the Department of Health and Human Services. These incidents include unanticipated problems in research that involve risk to subjects or others, serious or continuing noncompliance with federal policies or the requirements or determinations of the IRB, and any suspension or termination of IRB approval. The Principal Investigator and the Provost and Vice Chancellor for Academic Affairs will receive a copy of the report submitted by the IRB to OHRP.

Additional Resources and Further Information

The IRB web site includes information on the most up to date federal guidance on specific situations in human subjects research and how they apply to typical research scenarios at UNC Pembroke. In addition, the IRB website provides links to other sites that provide additional information on government regulations and resources for the protection of human subjects in research. Faculty members and Principal Investigators contemplating research proposals involving human subjects should examine the website and provided links for guidance applicable to their particular project.

References

Office for Human Research Protection, U.S. Department of Health & Human Services (OHRP) (2018). *45 CFR 46 – Protection of Human Subjects* (07/19/2018 ed.). Washington, DC: Government Printing Office. Retrieved April 10, 2019 from: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

OLD VERSION

Institutional Review Board for Research with Human Subjects (IRB)
Purpose and Scope of IRB Approval

The Institutional Review Board is required by federal law to review and approve ALL research proposals that involve human subjects; that is, any research involving people including adults, children and infants. Special protections are accorded to minors, pregnant women and fetuses, institutionalized populations, the mentally disabled, and economically and educationally disadvantaged persons.

The federal regulations define research as a systematic investigation, including testing and evaluation, designed to develop or contribute to generalized knowledge. A human subject is defined as a living individual about whom an investigator conducting research obtains personal data through intervention or interaction with the individual or identifiable private information.

Federal law requires that all research protocols involving human subjects must be reviewed and approved by an IRB, even if the proposal is not externally funded. The UNC Pembroke IRB must review any human subjects research conducted at UNC Pembroke regardless of outside approval. This includes all research with human subjects conducted at UNC Pembroke including faculty, staff and/or students as research subjects or by UNC Pembroke faculty, staff and or students at any location. Research conducted as part of a classroom exercise or a course assignment MAY be exempt from IRB review. However, the IRB Chair or designate must make that decision based upon a protocol review.

The Institutional Review board at UNC Pembroke ensures that all research that is undertaken protects participants from unreasonable risks to their health, general well-being or privacy. Specifically, the University is concerned that all research and related activities involving the use of human subjects:

4. Protect the rights and welfare of persons participating as subjects, including, but not limited to the protection of identifiable private information.
5. Use as subjects only persons who have freely given informed consent after being made aware of the potential risks and/or benefits of a particular research project, and
6. Allows participants advance knowledge of potential risks of participation and knowledge that these risks have been evaluated by an IRB.

Review and approval of all research protocols is the responsibility of the Institutional Review Board (IRB), a panel of UNC Pembroke faculty, administrators and a community representative. The IRB is responsible for protection of the rights, welfare and privacy of research subjects through an initial review and subsequent oversight of all human subjects research.

Under both federal and university policy, the IRB has the authority to approve proposed research, to require revisions in proposed research to ensure it includes safeguards to protect subjects, or to refuse to approve proposed research if the applicant cannot or will not revise the protocol to prevent identified risks to the subjects. Once the research is approved the IRB has the authority to monitor the research to ensure that research is conducted as approved. Additionally, multi-year research projects are required to be reviewed and re-authorized according to the review process outlined below.

All IRB reviews begin with an application (see application procedures below). Following an initial review of the application describing the nature of the research, a proposal may be:

- *Exempt* from further IRB review
- Appropriate for an *expedited review* by the chairperson of the IRB or a subcommittee of the IRB
- Subject to *full review* by the *full* IRB

Only the IRB Chair, or designee, can determine which type of review is applicable. Regardless of level of review, a record must be kept by the IRB of all research involving human subjects at UNC Pembroke. It is the goal of the UNC Pembroke IRB to support the development of protocols that protect human subjects and support research. Researchers with protocols that lack protection for human subjects will be offered guidance to make necessary modifications to augment approval. No proposal will be rejected without recommendations for modification and resubmission.

Further policy and procedure information, forms to be used for proposals, and links to other useful sites are available on the IRB web site at http://www.uncp.edu/irb. The current IRB Chair can be contacted by email at irb@uncp.edu.

UNC Pembroke Institutional Review Board (IRB) Policies and Procedures

IRB Membership

The Provost and Vice Chancellor for Academic Affairs appoints IRB members for Academic Affairs for three-year terms. The Institutional Review Board includes the Director of Sponsored Research (or delegate) and at least five faculty members. The members should reflect the diversity of the institution and the community. A minimum of two members should be experienced in human subjects research. There must be one non-scientist member and one member who is not affiliated with UNC Pembroke. A chair is elected at the first meeting of each academic year. Names of current IRB members and their email addresses are located on the IRB website http://www.uncp.edu/irb

No IRB member may participate in the review of a proposal in which the member has a conflict of interest. Specialists may be invited by the IRB to provide technical assistance, if the subject matter is deemed outside the expertise of the sitting IRB members.

Operating Procedures

The University IRB will review all research involving human subjects carried out at UNC Pembroke or by UNC Pembroke faculty, staff or students. The IRB is responsible for approving research protocols, requiring modifications, or disapproving research. The IRB is responsible for the development of all forms requesting review and guidelines for informed consent that reflect federal regulations. The IRB will notify researchers of their decisions by email. Additional written notification will be provided upon the request of the applicant.

The IRB will meet monthly during the academic year. The meeting schedule for each academic year will be discussed and set during the August meeting of each year. Announcement of a full Review Board meeting will be placed on the IRB website at least 5 working days in advance of each meeting. For a research protocol that requires a full board review, a majority of the membership must be present to consider any proposal and a majority vote is required for any Board action. For board meetings where a full board review of a protocol takes place, the principal investigator (or delegate) should attend to present a review of the research and answer any relevant questions posed by the committee.

The IRB will keep adequate records of all protocols and requests for continuing review, including decisions made. The minutes of each IRB meeting will include the names of members who attended, actions taken by the Board, the outcome of voting on research protocols including numbers of votes for and against, the rationale for requiring modifications to a protocol or informed consent process, and a summary of discussion of controversial issues and their resolution. Records of all protocols, requests for continuing review, and records of IRB reviews and meeting minutes will be kept on file for a minimum of three years.

IRB Proposal Submission and Review Procedures

An application for IRB review includes a completed IRB Protocol Application (available online at https://www.uncp.edu/academics/research/institutional-review-board/forms-and-guidelines) and all supporting materials. Supporting materials typically include all recruitment materials, consent forms, survey instruments, debriefing statements, data use agreements, and human subjects research training documentation (see 8-3.B.5). IRB applicants should submit one electronic copy of the application and all supporting materials to irb@uncp.edu. Additionally, one original signed copy of the application should be sent to the current IRB Chair via Campus Mail.

IRB review requests will be acknowledged by electronic mail within three business days of receipt. The IRB Chair or designee will evaluate the protocol and determine the required level of review and inform the Principal Investigator of this decision as soon as it can be determined. Based upon the Code of Federal Regulations, Title 45 Part 46, the UNC Pembroke IRB will utilize the following categories of review:

Exempt from Review

Projects that are traditionally exempt from an expedited or full IRB review include normal educational practices, educational tests, surveys, instruments, or observation of public behavior when subjects cannot be identified and the information gathered will not put 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. Applications that are exempt from review will be notified by electronic mail as soon as that decision is made.

Protocols that are developed for either instructional purposes or teaching research methodology and are not designed to contribute to generalized knowledge may be exempt from review. Under these circumstances the instructor assumes ethical and professional responsibility to monitor the progress of all research in the classroom. Research on vulnerable populations, including minors, pregnant women, fetuses, prisoners, seriously ill, and mentally incapacitated individuals may not be exempt from review. An Exempt Review determination does not imply that research subjects are exempt from human subjects protections.

Protocols that are approved as exempt from review are valid for three years. Researchers may request an extension beyond three years if necessary by contacting the IRB Chair and submitting an updated Protocol Application.

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 or interview methodologies. Expedited review may be used for these types of research regardless of the age of the subjects.

Expedited reviews are completed by the IRB Chair or designee and at least two additional IRB members. Expedited reviews are generally completed within two weeks. Minor modifications to the protocol may be requested by IRB members participating in the review during this review process. The applicant will be notified by electronic mail as soon as a decision is made.

Protocols that are approved through an expedited review are valid for one year. Researchers may request an extension beyond one year if necessary by contacting the IRB Chair and submitting an updated Protocol Application.

Full Review

Full IRB review includes 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. It also includes research that involves more than moderate exercise, research on individual or group characteristics or behavior that employs deception of the subjects or where they are placed under psychological or emotional stress, and research that poses potential physical, psychological, social, legal or other risks to the subjects.

Research targeting vulnerable populations, including minors (unless an expedited review is allowed), pregnant women and fetuses, institutionalized populations, the mentally disabled, and economically and educationally disadvantaged persons will receive a full review to insure that adequate protections are in place.

A protocol that will be reviewed by the full board will be assigned to the next available board meeting on the schedule, but no sooner than two weeks from submission in order to insure adequate time for the board members to conduct their review. The research protocol will be distributed electronically to all board members two weeks prior to the meeting. A majority of board members must be present at the review meeting. The Principal Investigator will be invited to present the research protocol and answer questions at this meeting. The protocol must be approved by a majority of the members present. Members of the IRB who vote to disapprove a protocol shall submit their reasons in writing to the IRB Chair. Protocols that are approved through a full review are valid for one year. Researchers may request an extension beyond one year if necessary by contacting the IRB Chair and submitting an updated Protocol Application.

Changes to Existing Protocols, Adverse Events, and Renewal Procedures

Regardless of the level of review or existing approval, any changes made to the research protocol must be submitted to the IRB for review in writing prior to their implementation, as they may affect the status of a review. Additionally, the Principal Investigator is responsible for reporting any adverse or unanticipated events that may occur during their research to the IRB immediately, and no later than one week from their occurrence.

In order to submit changes to an existing protocol, Principal Investigators should add the proposed changes to their IRB Protocol Application and submit it electronically to the IRB Chair.

In order to apply for a renewal of an existing protocol, the Principal Investigator should notify the IRB no later than 30 days prior to the expiration of their approval. Renewal requests should include the submission of an electronic copy of the approved IRB Protocol Application with changes added to the file. In addition, any new recruitment materials, consent forms, or other supplementary materials should be submitted with the renewal application.

It is the Principal Investigator's responsibility to keep an electronic copy of their approved IRB Protocol Application in order to facilitate the submission of changes and renewal requests.

Training on Human Subjects Research

To provide investigators with up-to-date information about the regulatory requirements for conducting research, the IRB requires that each researcher review core concepts for the responsible conduct of research with human subjects. In order to submit an IRB, Principal Investigators must have completed an OHRP approved training within the last 2 years and submitted documentation to the IRB Chair. The IRB will provide a link to an approved web-based training module on the IRB https://www.uncp.edu/academics/research/institutional-review-board).

Research Misconduct in Human Subjects Research

The IRB will promptly report any potential research misconduct involving human subjects by Principal Investigators affiliated with UNC Pembroke to the Provost and Vice Chancellor for Academic Affairs. The procedures for handling an allegation of research misconduct are defined in the section below on "Misconduct Related to Research."

Additionally, the IRB is required by federal law to promptly report certain incidents to the Office for Human Research Protections (OHRP), a division of the Department of Health and Human Services. These incidents include unanticipated problems in research that involve risk to subjects or others, serious or continuing noncompliance with federal policies or the requirements or determinations of the IRB, and any suspension or termination of IRB approval. The Principal Investigator and the Provost and Vice Chancellor for Academic Affairs will receive a copy of the report submitted by the IRB to OHRP.

Additional Resources and Further Information

The IRB web site includes information on the most up to date federal guidance on specific situations in human subjects research and how they apply to typical research scenarios at UNC Pembroke. In addition, the IRB website provides links to other sites that provide additional information on government regulations and resources for the protection of human subjects in research. Faculty members and Principal Investigators contemplating research proposals involving human subjects should examine the website and provided links for guidance applicable to their particular project.