**North Carolina Division of Public Health**

Institutional Review Board Protocol

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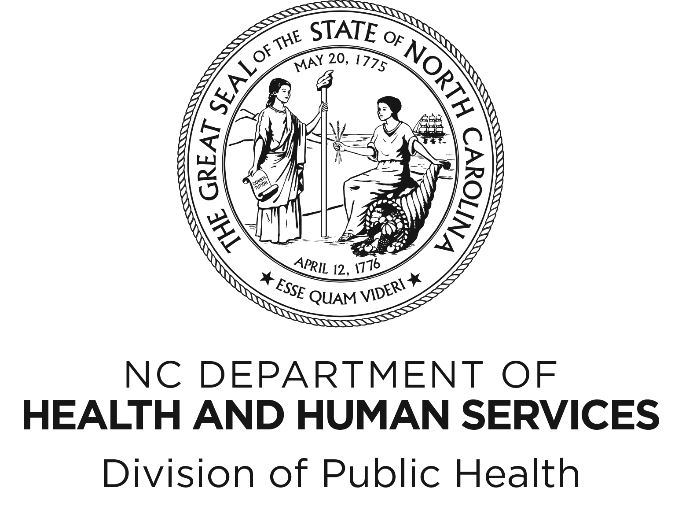


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# 1.0 INTRODUCTION

* 1. The North Carolina Division of Public Health (NC DPH), hereinafter referred to as the “institution,” is the public health agency for the State of North Carolina. The mission of NC DPH is to serve the people of North Carolina by promoting and contributing to the highest possible level of health for the people of North Carolina. To fulfill this mission, it is appropriate and necessary for the institution to conduct research, which is the practice of systematic scientific investigation that enhances generalized knowledge. In carrying out research, it is vital that transparency and the trust of the public be maintained and that human subjects who may be involved are provided with all reasonable protections of their rights. The institution believes that an Institutional Review Board protocol, as outlined in this document, is the optimal way to meet this need.
  2. NC DPH hereby gives assurance that it will comply with the Belmont Report and the United States Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 C.F.R. 46) as specified below.
  3. The responsibility for providing review and continuing surveillance of research activities involving human subjects is delegated by the Director of NC DPH to the appointed Division of Public Health Institutional Review Board, hereinafter the “DPH IRB.”
  4. The DPH IRB shall operate in accordance with this protocol.

# DEFINTIONS

* 1. A Notice Letter is the official notification to the applicant that the project protocol submitted by the applicant to the IRB has been reviewed and a determination has been made by the IRB in accordance with the guidelines contained herein. A notice letter shall, at minimum, include the DPH IRB’s federal-wide assurance (FWA) number, the date of determination, the name of the principal investigator, and the name of the study. A Notice Letter documenting IRB approval shall also include: confirmation that the study was reviewed and approved by the DPH IRB; whether the study is subject to continuing review; and, if the research study is subject continuing review, how often review will be conducted.
  2. Research means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purpose of the regulations set forth in this protocol, whether or not the activities are supported or funded under a program that is considered research for other purposes. Research is to be distinguished from service activities of which the primary function is to fulfill the duties assigned to NC DPH under state law or which respond to specific individual or community public health needs. In accordance with federal regulations, the activities identified in 45 C.F.R. 46.102(l) shall not be considered human subjects research and are not be subject to IRB review.
  3. Human Subject means as defined at 45 CFR 46.102(e)(1).
  4. IRB Approval means the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional, state, and federal requirements.
  5. Legally Authorized Representative is as defined at 45 CFR 46.102(i).
  6. Minimal Risk is as defined at 45 CFR 46.102(j).
  7. Minor Change[[1]](#footnote-1) means a change that neither materially increases risk, nor materially decreases benefit, nor materially decreases scientific merit.
  8. Office of Human Research Protections (OHRP) is part of HHS and provides oversight and leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by HHS.
  9. Unanticipated Problem Involving Risks to Human Subjects or Others[[2]](#footnote-2) includes any incident, experience, or outcome that meets all of the following criteria:
     1. The problem is unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved study protocol and informed consent document, and given the characteristics of the subject population being studied;
     2. The problem is related to the research or there is a reasonable possibility that the problem may have been caused by the procedures involved in the research; and
     3. The problem suggests that the research places human subjects at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

## Serious or Continuing Noncompliance means as follows:

* + 1. “Serious noncompliance” shall include any noncompliance with 45 C.F.R. 46, applicable state law, or requirements set forth by the DPH IRB that significantly increase risk to human subject participants in the research, significantly decreases potential benefits, or compromises the integrity of the institution and its research.
    2. “Continuing noncompliance” shall include a pattern of noncompliance with requirements set forth by 45 C.F.R. 46, applicable state law, or the DPH IRB that the research investigator knew or should have known about, and that:
       1. Indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of human subjects;
       2. Suggests a likelihood that noncompliance will continue without intervention; or
       3. Compromises the scientific integrity of a study such that important conclusions can no longer be reached.

# ETHICAL PRINCIPLES

* 1. This institution is guided by the ethical principles set forth in the report produced by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the “Belmont Report”).
  2. In addition, the requirements set forth in 45 C.F.R. 46 will be met for all applicable HHS-funded research.

# INSTITUTIONAL POLICY

## Scope

* + 1. The institution has established and will maintain one IRB (the DPH IRB) in accordance with 45 CFR 46. The DPH IRB has the responsibility and authority to review, approve, disapprove, or require changes in research activities involving human subjects. The institution bears full responsibility for complying with federal, state, or local laws as they may relate to research covered by this policy. The institution bears full responsibility for the performance of all research involving human subject covered that is covered by this policy.

## Research subject to DPH IRB review

* + 1. This policy is applicable to all research involving human subjects if any of the following applies:
       1. The research is sponsored by this institution; or
       2. The research is conducted by or under the direction of any employee of this institution as part of his or her official responsibilities; or
       3. The research is conducted by or under the direction of any employee or agent of this institution using any property, resources, or facilities belonging to this institution.

## Cooperative research and single IRB (“sIRB”) review

* + 1. This institution will comply with the requirements set forth in 45 CFR 46.114 regarding cooperative research and review by a single IRB.

## Reliance Agreements

* + 1. When research covered by this policy is conducted at or in cooperation with another entity, this institution may enter into a Reliance Agreement (sometimes also referred to as a “Cooperative Agreement” or “IRB Authorization Agreement”) that permits one IRB (the “relying IRB”) to cede review to another IRB (the “reviewing IRB,” or “IRB of record”). Such agreements shall be in writing, signed by the DPH IRB Chair or the institution’s signatory official, and signed by the correlative signatory officials of the other cooperating institutions. A copy of the signed Reliance Agreement shall be retained by NC DPH.

## Continuing review

* + 1. The DPH IRB’s review of research on a continuing basis will be conducted at intervals appropriate to the degree of risk, but not less often than once per year. At the time of continuing review, the DPH IRB may request verification from sources other than the research investigator to confirm that no material changes have occurred since the last review.
    2. 45 C.F.R. 46.109(f) identifies situations in which continuing review is not required; however, the DPH IRB may, at its discretion, voluntarily undertake continuing review of a research study when the institution determines that continuing review is necessary. In such instances, the DPH IRB shall comply with the requirements of 45 C.F.R. 46.115(a)(3) by documenting the rationale for conducting continuing review of research that otherwise would not require continuing review.

## Exempt research activities

* + 1. Research activities may be found to be exempt when the DPH IRB reviews the study protocol and makes the determination that the only involvement of human subjects will be in one or more of the categories of exempt research activities defined at 45 C.F.R. 46.104, unless the research is covered by Subpart B, C, or D of 45 C.F.R. 46 pertaining to additional protection for research activities involving fetuses, pregnant women, human in vitro fertilization, prisoners, and children.

## Informed consent

* + 1. It is the policy of the institution that unless consent has been specifically waived by the DPH IRB in accordance with 45 CPR 46.116(f), no research investigator shall involve any human being as a subject in research unless the research investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. If consent is otherwise required under state or federal law, the DPH IRB is not authorized to waive consent.

## Recordkeeping

* + 1. The IRB Administrator shall be responsible for maintaining documentation of IRB activities in accordance with the recordkeeping requirements established at 45 C.F.R. 46.115.

## Changes to the DPH IRB protocol

* + 1. The institution shall provide each DPH IRB member and the Director of the institution with a copy of this policy and copies of any future modifications which may be made to this policy.

## Annual review of institutional policy and practices

* + 1. This institution will exercise appropriate administrative oversight carried out at least annually to ensure that its practices and policies designed for the protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the requirements of 45 CFR 46.

# RESPONSIBILITIES OF RESEARCH INVESTIGATORS

## Determination of human subject involvement

* + 1. Research investigators, with the input and assistance of their respective NC DPH Branch Heads and Section Chiefs, shall make a determination as to whether their proposed research will involve human subjects. Research involves human subjects when the research seeks to obtain information about living individuals.[[3]](#footnote-3)
    2. When it is not clear whether the research involves human subjects the research investigators should seek assistance from the DPH IRB Chair in making this determination.

## Preliminary determination of exemption eligibility

* + 1. The research investigators, with the input and assistance of their respective NC DPH Branch Heads and Section Chiefs, shall make the preliminary determination of whether their research, which involves human subjects, is exempt under Section 4.6 of this policy.
    2. When research investigators make the preliminary determination that their research is exempt from DPH IRB review, the research investigators shall notify the DPH IRB Chair of the preliminary determination and submit an Exemption Determination Form (Appendix C) to the DPH IRB Chair and DPH IRB Administrator (contact information listed in Appendix A). If the DPH IRB Chair disagrees with the research investigator’s preliminary determination then the DPH IRB Chair may require that the researcher complete and submit the standard DPH IRB application to the DPH IRB for review.

## Preparation of the DPH IRB application

* + 1. If research investigator’s research study is determined to be non-exempt from IRB review in accordance with the process described in Section 5.2 of this protocol, and is subject to DPH IRB review in accordance with Section 4.1 of this protocol, the research investigator shall prepare and submit to the DPH IRB Chair and DPH IRB Administrator a DPH IRB Application Form (Appendix D).
    2. In the application, the research investigator shall provide a complete description of the proposed research. The research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed.
    3. The DPH IRB application must also be signed by the principal investigator’s Section Chief, who will assist the research investigator in reviewing the research protocols for ethical consideration and scientific merit prior to submitting an application to the DPH IRB.

## Submission of the DPH IRB Application Form

* + 1. Research investigators shall submit their Application Form by sending an email addressed to both the DPH IRB Chair and the DPH IRB Administrator (contact information available in Appendix A).
    2. Research investigators shall submit their Application Form no later than six weeks before the next regularly-scheduled quarterly DPH IRB meeting in order for the application and protocol to be considered at the next DPH IRB meeting. A list of upcoming DPH IRB meeting dates can be obtained by emailing the DPH IRB Administrator or on the DPH Office of Regulatory and Legal Affairs Sharepoint site.
    3. **Federal regulations prohibit researcher investigators from beginning work on their projects before receiving approval from the IRB.**

## Complying with IRB decisions

* + 1. Research investigators shall be responsible for complying with all DPH IRB decisions, conditions, and requirement; the DPH IRB protocol; the Belmont Report; and the 2018 Revised Common Rule.

## Obtaining informed consent

* + 1. Research investigators shall be responsible for obtaining informed consent in accordance with the requirements set forth in 45 C.F.R. 46.116(a) and 46.116(b), and for ensuring that no human subject will be involved in the research before his or her informed consent is obtained.
    2. Researchers may obtain broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Broad consent serves a substitute for traditional informed consent only in specific circumstances and only when obtained in compliance with the requirements identified in 45 C.F.R. 46.116(d).

## Documentation of informed consent

* + 1. Research investigators shall be responsible for ensuring that the informed consent of human subjects or their legally authorized representatives is documented in accordance with the requirements set forth in 45 C.F.R. 46.117.
    2. Research investigators shall be responsible for retaining copies of each human subject’s signed consent form. Research investigators shall store the signed consent forms in a secure manner that is described in the research study’s DPH IRB-approved application.

## Submission of research study progress reports

* + 1. Research investigators shall be responsible for reporting the progress of the research to the DPH IRB Chair, as often as and in the manner required by the DPH IRB.

## Reporting injuries to human subjects

* + 1. Research investigators shall be responsible for promptly reporting to the DPH IRB Chair and the DPH IRB Administrator any injury to a human subject who is participating in the researcher’s project. Such reports shall be made by sending an email and making a phone call to the DPH IRB Chair and DPH IRB Administrator using the contact information provided in Appendix A.
    2. At the request of the DPH IRB Chair, the research investigator shall provide a written summary of the injury or injuries. The research investigator shall cooperate with the DPH IRB’s requests for additional information and shall cooperate in the event that the DPH IRB determines it is necessary to further report the matter to NC DPH officials, OHRP, or other parties.

## Reporting unanticipated problems

* + 1. Research investigators shall be responsible for promptly reporting unanticipated problems involving risks to human subjects or others (as defined in Section 2.7 of this protocol) to the DPH IRB Chair. Such reports shall be made by sending an email and making a phone call to the DPH IRB Chair and DPH IRB Administrator using the contact information provided in Appendix A.
    2. At the request of the DPH IRB Chair, the research investigator shall provide a written summary of the unanticipated problem. The research investigator shall cooperate with the DPH IRB’s requests for additional information or shall cooperate in the event that the DPH IRB determines it is necessary to further report the matter to NC DPH officials, OHRP, or other parties.

## Reporting noncompliance

* + 1. Research investigators shall be responsible for promptly reporting to the DPH IRB Chair any serious or continuing noncompliance, as defined in Section 2.10 of this protocol. Such reports shall be made by sending an email and making a phone call to the DPH IRB Chair and DPH IRB Administrator using the contact information provided in Appendix A.
    2. At the request of the DPH IRB Chair, the research investigator shall provide a written summary of the serious or continuing noncompliance. The research investigator shall cooperate with the DPH IRB requests for additional information and shall cooperate in the event that the DPH IRB determines it is necessary to further report the matter to NC DPH officials, OHRP, or other parties.

## Changes in research

* + 1. Research investigators shall not initiate any changes to their research without first informing the DPH IRB and obtaining DPH IRB approval of the proposed changes, except when changes are necessary to eliminate apparent immediate hazards to human subjects.
       1. When changes are made to eliminate apparent immediate hazards to human subjects the research investigators shall promptly notify the DPH IRB Chair and DPH IRB Administrator of these changes. Such reports shall be made by sending an email and making a phone call to the DPH IRB Chair and DPH IRB Administrator using the contact information provided in Appendix A.
       2. If a researcher intends to make a change to their research that is not in response to an apparent immediate hazard, he or she should submit a DPH IRB Research Modification Form (Appendix E) to the DPH IRB Chair and DPH IRB Administrator. The DPH IRB Research Modification Form must be reviewed and approved by the DPH IRB before the researcher is permitted to implement the changes.
    2. The DPH IRB may use expedited review if the change is limited to a minor change, as defined in Section 2.7 of this protocol, to a previously approved research study during the period for which approval of the study is authorized.
    3. Upon review of the proposed changes in the research, the DPH IRB may undertake the same actions as described in Section 9.6 of this protocol.

## Notifying the IRB Chair of investigations of new drugs

* + 1. Research investigators shall be responsible for notifying the United States Food and Drug Administration (FDA) and the DPH IRB Chair whenever it is anticipated that an investigatory new drug or new device exemption will be required.

## Required training

A. Researcher investigators who are employed by NC DPH shall be required to complete the CITI course curriculum described in Appendix G. The CITI training must be completed before the DPH IRB will issue a Notice Letter approving the proposed research and authorizing the research investigator to begin his or her research activities.

# RESPONSIBILITIES OF THE DPH IRB CHAIR

## Determinations concerning exemptions and method of review

* + 1. The DPH IRB Chair shall receive from researcher investigators a DPH IRB Application for all proposed research that involves human subjects.
    2. When a research investigator submits a DPH IRB Exemption Determination Form, the DPH IRB Chair shall review the submission and make a determination about whether the proposed research is exempt.
    3. The DPH IRB Chair may determine that the research may require IRB review but that, pursuant to Section 4.2 of this policy, the research is not subject to the jurisdiction of the DPH IRB, specifically.
    4. The DPH IRB Chair shall determine whether the non-exempt research meets the criteria necessary for expedited review as set forth in 45 C.F.R. 46.110 and described in Section 9.4 of this protocol, or if the research requires full committee review using the process described in Section 9.5 of this protocol.
    5. The DPH IRB Chair shall keep research investigators aware of decisions and administrative processes affecting the researchers’ respective projects.

## Unanticipated problems

* + 1. The DPH IRB Chair is the party designated to receive reports from research investigators on unanticipated problems, to assess whether an unanticipated problem has occurred, to notify the DPH IRB of reported unanticipated problems, and to make reports to OHRP when necessary.
    2. When the DPH IRB Chair receives a report from a research investigator that an unanticipated problem is believed to have occurred, the DPH IRB Chair shall investigate and assess the situation using the definition of “unanticipated problem” provided in Section 2.7 of this protocol as well as any available guidance published by OHRP.
       1. If the situation is found to constitute an unanticipated problem then the DPH IRB Chair shall promptly report the matter to OHRP. A copy of the report shall be provided to the DPH IRB Administrator for recordkeeping. The report should include, at minimum:
          1. Name of the institution conducting the research;
          2. Title of the research project;
          3. Name of the principal investigator;
          4. The study number assigned to the project by the reviewing IRB;
          5. A detailed description of the problem; and
          6. A corrective action plan that the institution or investigator plans to undertake to address the problem.
       2. If the situation is determined not to be an unanticipated problem then the DPH IRB Chair shall document his or her analysis and determination in writing. A copy of the document shall be provided to the DPH IRB Administrator for recordkeeping. The DPH IRB Chair may, at his or her discretion, assign a corrective action plan even when it is determined that an unanticipated problem did not occur.
       3. The DPH IRB Chair shall notify the DPH IRB of the matter at the next regularly-scheduled DPH IRB meeting by providing the DPH IRB members with a copy of either:
          1. The DPH IRB Chair’s report to OHRP; or
          2. The DPH IRB Chair’s written documentation of his or her the determination that the situation was not an unanticipated problem.
    3. If the research investigator has developed a corrective action plan to address the issue that was reported to the DPH IRB Chair as an unanticipated problem and requires changes to the study protocol then the DPH IRB shall determine whether:
       1. The corrective action plan involves only minor changes to the research and may therefore undergo expedited review; or
       2. The corrective action plan involves more than minor changes to the research and therefore requires full committee review.

## Serious or continuing noncompliance

* + 1. The DPH IRB Chair is the party designated to receive reports on serious or continuing noncompliance, to assess whether serious or continuing noncompliance has occurred, to notify the DPH IRB of reported serious or continuing noncompliance, and to make reports to OHRP when necessary.
    2. When the DPH IRB Chair receives a report from a research investigator or another party that serious or continuing noncompliance is believed to have occurred, the DPH IRB Chair shall follow the steps outlined in Section 6.2(B) and 6.2(C) of this protocol.

# RESPONSIBILITES OF THE DPH IRB ADMINISTRATOR

## Administration

* + 1. The DPH IRB Administrator shall oversee the administration of the DPH IRB, which may include tasks such as scheduling DPH IRB meetings, reserving meeting space, and developing training for DPH IRB members.
    2. The DPH IRB Administrator shall assist with tracking study approvals, tracking reliance agreements, and scheduling continuing reviews to prevent lapses in IRB approval.

## Support to the DPH IRB Chair

* + 1. The DPH IRB Administrator shall, as needed, shall provide support to the DPH IRB in carrying out his or her responsibilities.

## Registering the DPH IRB with OHRP

* + 1. The DPH IRB Administrator shall be responsible for maintaining and updating the DPH IRB’s registration with OHRP in compliance with the requirements set forth in 46 C.F.R. 46.505.

## Registering the institution’s FWA

* + 1. The DPH IRB Administrator shall be responsible for maintaining and updating the institution’s FWA in accordance with 45 C.F.R. 46.103.

## Recordkeeping

* + 1. The DPH IRB Administrator shall be responsible for maintaining records that document the activities and decisions of the DPH IRB as set forth in 45 C.F.R. 46.115 and Section 4.8 of this protocol. These records shall include, but are not limited to, the following:
       1. Copies of all research proposals reviewed, approved consent forms, progress reports submitted by investigators, and reports of injuries to subjects;
       2. Minutes of IRB meetings;
       3. Records of continuing review activities;
       4. Copies of official correspondence between the DPH IRB and investigators, including Notice Letters;
       5. Reliance agreements to which the DPH IRB is a party;
       6. Current list of DPH IRB members;
       7. Statements of significant new study findings that are provided by research investigators to subjects;
       8. The rationale for findings by the DPH IRB Chair that research that has been submitted for expedited review involves more than minimal risk and must therefore be reviewed by the full DPH IRB committee; and
       9. Documentation specifying the responsibilities of this institution and the DPH IRB to ensure compliance with the requirements of 45 C.F.R. 46.
    2. The DPH IRB Administrator may maintain these documents in printed or electronic form so long as the records can be easily accessed and timely presented for inspection at OHRP's request.

## DPH IRB Administrator position vacant

* + 1. When the DPH IRB Administrator role is not filled the responsibilities assigned to that position shall fall to the DPH IRB Chair or his or her designee until the time when a new DPH IRB Administrator can be installed.

# IRB STRUCTURE AND MEMBERSHIP

## Institutional establishment of the DPH IRB

* + 1. The DPH IRB is established within the NC DPH to review research involving human subjects.

## Appointment to the DPH IRB

* + 1. The DPH IRB Institutional Official shall designate an individual to serve as the DPH IRB Chair.
    2. The DPH IRB Institutional Official, in consultation with the DPH IRB Chair, shall appoint members to the DPH IRB.
    3. Appointment to the DPH IRB shall be for a three-year term.

## Membership

## Principles

## The DPH IRB shall be comprised of members from diverse backgrounds to promote complete and adequate review of research activities covered by this policy and to ensure the professional competence necessary to review the specific research activities that are routinely subject to DPH IRB review.

* + - 1. The DPH IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds, including consideration of the race, gender, and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safe-guarding the rights and welfare of human subjects.
      2. When research is reviewed involving a category of vulnerable subjects (e.g., children, individuals with impaired decision-making capacity, or economically or educationally disadvantaged individuals), the IRB shall include in its reviewing body one or more individuals who have as a primary concern the welfare of these subjects.

## DPH IRB compositional requirements

## The DPH IRB shall comply with the IRB membership requirements set forth in 45 CFR 46.107, as well as the following:

* + - 1. The DPH IRB shall have at least nine members, including the DPH IRB Chair.
      2. At least five members shall be selected from DPH Sections that are regularly engaged in research involving human subjects. No more than two members shall be from the same Section.
      3. The DPH IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
      4. The DPH IRB shall include male and female members.
      5. The DPH IRB shall include at least one individual with expertise in epidemiology or biostatistics.
      6. The DPH IRB shall include at least one individual with expertise in clinical social work or public health nursing.
      7. The DPH IRB shall include at least one individual who is not otherwise affiliated with NC DPH and who is not part of the immediate family of any NC DPH employee.
      8. The DPH IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the DPH IRB. These individuals may not vote with the DPH IRB.
    1. Disqualification
       1. Members of the DPH IRB who have a conflicting interest in a project that is under consideration by the DPH IRB shall not participate in the DPH IRB's initial or continuing review of that project. Any member who is named as a principal investigator or co-investigator on a project shall be deemed to have a conflict of interest. Other sources of conflicting interest are possible and members of the DPH IRB are encouraged to excuse themselves from review of any project where they deem a conflict of interest is possible. Conflicts of interests and recusals shall be documented in the DPH IRB meeting minutes.
    2. Training and resources
       1. The institution shall provide the resources necessary to ensure that all DPH IRB members receive suitable training for their duties on the DPH IRB and are kept abreast of current issues and new regulations. Such training shall include completion of the CITI course curriculum described in Appendix G.

# RESPONSIBILITIES OF THE DPH IRB

## Responsibilities and authority

* + 1. The DPH IRB shall have the responsibility to review and the authority to approve, require modification in, or disapprove all proposed research activities described in the submitted DPH IRB Application Form. The DPH IRB shall also have the responsibility and the authority to approve, require modification in, or disapprove any previously-approved research or a proposed change to a previously-approved research study.
    2. The DPH IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the DPH IRB's decisions, conditions, and requirements or the Common Rule.
       1. When a research study is terminated or suspended, the DPH IRB, through the DPH IRB Chair, shall provide the research investigator with a written explanation of the decision to terminate or suspend.
    3. The DPH IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent complies with the requirements set forth in 45 C.F.R. 46.116. The DPH IRB may require that information, in addition to that which is specifically required under 45 C.F.R. 46.116, be given to the subjects when in the DPH IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
    4. The DPH IRB shall require documentation of informed consent or may waive documentation in accordance with 45 C.F.R. 46.117 and Section 4.7 of this protocol.
    5. The DPH IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure DPH IRB approval of the research activity. If the DPH IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
    6. The DPH IRB shall conduct continuing review of research at intervals determined appropriate given the degree of risk involved in the research, but not less often than once per years, unless continuing review of the research is not required under 45 C.F.R. 46.109 and Section 4.5 of this protocol.
    7. The DPH IRB shall have the authority to observe or have a third party observe the consent process and the research.
    8. The DPH IRB may, at its sole discretion, conduct random audits of research records to ensure that research approved by the DPH IRB is being carried out in accordance with state and federal law and any requirements that were established by the DPH IRB at the time of the study’s approval.
    9. The DPH IRB shall have the authority and responsibility for promptly reporting information to OHRP on a variety of issues. In conjunction with this requirement, the DPH IRB must be prepared to receive and act on information received from a variety of sources, such as human subjects, research investigators, or other departmental staff.

## Meetings

* + 1. The DPH IRB shall convene at least once per quarter to conduct full committee review of applications. The DPH IRB shall not be required to hold a quarterly meeting if it has not received any new research to review.
    2. The DPH IRB shall also meet at the call of the DPH IRB Chair when the Chair judges the meetings to be necessary or advantageous, or at the call of the DPH IRB Chair upon the receipt of a joint written request by three or more DPH IRB members.
    3. Ideally, meetings of the DPH IRB will be convened with members attending in person; however, members may participate in meetings by joining through videoconference or teleconference with the permission of the DPH IRB Chair.
    4. DPH IRB Application Form submissions shall be distributed to all DPH IRB members at least two weeks before the next regularly-scheduled DPH IRB meeting at which those applications will be reviewed.
    5. When it is determined that consultants or experts will be required to advise the DPH IRB in its review of proposed research then the application form shall also be distributed to the consultants or experts prior to the meeting.
    6. Full committee review of research requires a quorum consisting of the majority of the members of the DPH IRB, including at least one member whose primary concerns are in nonscientific areas.
    7. If a quorum is present at the start of a meeting but is then lost before the meeting ends then any business requiring the vote of the DPH IRB- including the review of a research study, discussion of the research study, and voting on the approval of the research study- shall be tabled until the next meeting when a quorum can be achieved.
    8. No DPH IRB member may participate in the DPH IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the DPH IRB.
    9. Except as otherwise covered in this policy, all convened IRB meetings shall be conducted under and pursuant to Robert’s Rules of order.

## Procedures for determining appropriate method of review

* + 1. The DPH IRB Chair shall be responsible for determining whether a non-exempt research study can undergo expedited review or requires full committee review. The DPH IRB Chair shall make these determinations using the process outlined in Section 6.1 of this protocol.

## Expedited review

* + 1. The DPH IRB may use the expedited review procedure when permitted pursuant to 45 CFR 46.110.
    2. Under an expedited review procedure, the review may be carried out by the DPH IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the DPH IRB.
    3. In conducting an expedited review of research, the DPH IRB Chair or his or her designee(s) may exercise all of the authorities of the DPH IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in 45 C.F.R. 46.108(b).
    4. The DPH IRB Chair or his or her designee shall provide updates on recent expedited review activities at the regularly-scheduled meetings of the full DPH IRB.

## Requirements for research study approval

* + 1. In order to approve research covered by this policy, the DPH IRB shall comply with the requirements set forth in 45 CFR 46.111 and determine that all of the following requirements are satisfied:
       1. Research investigators and study staff have the qualifications necessary to conduct the research.
       2. Risks to subjects are minimized:
          1. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk; and
          2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
       3. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the DPH IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The DPH IRB should not consider possible long-range effects of applying knowledge gained in the research (*e.g.,* the possible effects of the research on public policy) as among those research risks or benefits that fall within the purview of its responsibility.
       4. Selection of subjects is equitable. In making this assessment the DPH IRB should take into account the purposes of the research and the setting in which the research will be conducted. The DPH IRB should be particularly cognizant of the special problems that may arise in research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, and whether additional safeguards have been included to protect the rights and welfare of these subjects.
       5. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, 45 C.F.R. 46.116. The DPH IRB should consider the following:
          1. Whether the consent forms will be translated for any non-English speaking human subjects who may be involved in the research;
          2. Whether the consent forms identify situations in which confidentiality may be broken by a research investigator when the research investigator gains information that suggests a potential risk to a human subject or others, or in order to comply with federal or state law; and
          3. If requested by the research investigator, whether elements of informed consent may be waived in accordance with 45 C.F.R. 46.116(f) and Section 4.7 of this protocol.
       6. Informed consent will be documented appropriately. The DPH IRB should consider the following:
          1. If requested by the research investigator, whether documentation of informed consent may be waived in accordance with 45 C.F.R. 46.117(c).
       7. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
       8. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
       9. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
          1. When the research being reviewed involves pregnant women, human fetuses, neonates, prisoners, or children, the DPH IRB shall conduct its review in accordance with the additional requirements set forth under 45 C.F.R. Subparts B, C, and D, as described in Sections 10.0, 11.0, and 12.0 of this protocol.

## Approval, approval with conditions, and disapproval by full DPH IRB committee review

* + 1. Upon review of the DPH IRB Application Form, which includes consent forms, survey instruments, and recruitment materials, the DPH IRB may approve or disapprove a study, or may approve the study with conditions.
       1. Disapproval. If a study is disapproved, the DPH IRB Chair shall return the study protocol to the research investigators along with a written explanation of the DPH IRB’s decision not to approve.
       2. Approval with conditions. If a study is approved with conditions, the DPH IRB shall provide the research investigators with a written explanation of the conditions that must be met before the study can be considered approved and research activities can begin. The DPH IRB Chair shall not certify a study approved with conditions until the Chair has determined those conditions have been met. **The research investigators shall not begin research activities that involve human subjects until they have met the conditions required by the DPH IRB and have received a Notice Letter of approval from the DPH IRB Chair.**
       3. Approval. For a study to be approved, it must receive the approval of a majority of the members present at the convened meeting and must be determined to meet the requirements described in Section 9.5 of this protocol. If a study is approved, the DPH IRB Chair shall provide the research investigators with a Notice Letter documenting the approval.

## Suspension or termination of IRB approval or disapproval of research at the time of continuing review

* + 1. Pursuant to 45 C.F.R. 46.113, the DPH IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or the Common Rule.
    2. When the DPH IRB decides to suspend or terminate approval of a research study it shall document its decision in writing. A copy of the document shall be provided to the research investigator(s) and to the DPH IRB Administrator for recordkeeping.
    3. Any suspension or termination of approval shall be reported promptly to appropriate officials (which may include the DPH IRB Institutional Official, DPH Branch Heads, and/or DPH Section Chiefs) and, as the law requires, to OHRP.
       1. Reports to appropriate institutional officials shall be made by the DPH IRB Chair and may be made in the manner that the DPH IRB Chair deems appropriate.
       2. Reports to OHRP shall be made by the DPH IRB Chair and include:
          1. Name of the institution conducting the research;
          2. Title of the research project;
          3. Name of the principal investigator;
          4. The study number assigned to the project by the reviewing IRB;
          5. A detailed description of the problem; and
          6. The actions that the institution or investigator plans to undertake to address the suspension or termination.
    4. The DPH IRB should also consider any additional steps that may need to be taken once a research study is terminated or suspended, such as notification to research participants of the study’s termination or suspension.

# ADDITIONAL PROTECTIONS FOR PREGNANT WOMEN, HUMAN FETUSES, AND NEONATES INVOLVED IN RESEARCH

* 1. This protocol hereby incorporates by reference 45 C.F.R. Subpart B, with all subsequent amendments, which outlines additional protections and considerations for research involving pregnant women, human fetuses, and neonates.
  2. The DPH IRB shall review research covered by this Subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other requirements set forth under 45 C.F.R. 46.

# ADDITIONAL PROTECTIONS PERTAINING TO BIOMEDICAL AND BEHAVIORAL RESEARCH INVOLVING PRISONERS AS SUBJECTS

* 1. This protocol hereby incorporates by reference 45 C.F.R. Subpart C, with all subsequent amendments, which outlines additional protections and considerations for biomedical and behavioral research involving prisoners as human subjects.
  2. The DPH IRB shall review research covered by this Subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other requirements set forth under 45 C.F.R. 46.
  3. In addition to satisfying the requirements set forth in 45 C.F.R. 46.107 the DPH IRB, in carrying out responsibilities under this part with respect to reviewing research covered by this subpart, shall also meet the following specific requirements:
     1. A majority the DPH IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the DPH IRB; and
     2. In order to review research involving prisoners, at least one member of the DPH IRB must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than IRB only one of the reviewing IRBs must satisfy this requirement.

# ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED AS SUBJECTS IN RESEARCH

* 1. This protocol hereby incorporates by reference 45 C.F.R. Subpart C, with all subsequent amendments, which outlines additional protections and considerations for research involving children as human subjects.
  2. The DPH IRB shall review research covered by this Subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other requirements set forth under 45 C.F.R. 46.

# APPENDIX A: DPH IRB CONTACT INFORMATION

**DPH IRB Chair**

Virginia Niehaus

Email: Virginia.niehaus@dhhs.nc.gov

Phone: 919-707-5006

**DPH IRB Administrator**

Kirsten Leloudis

Email: Kirsten.leloudis@dhhs.nc.gov

Phone: 919-707-5179

**DPH IRB Institutional Official**

Mark Benton

Email: Mark.benton@dhhs.nc.gov

Phone: 919-707-5000

# APPENDIX B: DPH IRB MEMBERSHIP ROSTER

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DPH IRB 2020 Membership** | | | | |
|  | First Name | Last Name | Scientist (S) or Non-scientist (N) | DPH Employee (DPH) or Community Member (C) |
| 1. | Virginia | Niehaus | N | DPH |
| 2. | Yvonne | Torres | N | C |
| 3. | Chandrika | Rao | S | DPH |
| 4. | Carol | Tyson | S | DPH |
| 5. | Kathryn | Dail | S | DPH |
| 6. | Scott | Proescholdbell | S | DPH |
| 7. | Cardra | Burns | N | DPH |
| 8. | Victoria | Mobley | S | DPH |
| 9. | Scott | Shone | S | DPH |

# APPENDIX C: EXEMPTION DETERMINATION FORM

**NC Division of Public Health**

**Institutional Review Board for the Health and Safety of Human Subjects**

**DPH IRB Exemption Determination Form**

This form should be used when DPH staff, in consultation with their Section Chief and/or Branch Head, believe that their proposed research activity is exempt according to the federal regulations at 45 CFR 46.104. This form should be submitted to the DPH IRB Chair and the DPH IRB Administrator by email. *Please note that research that is exempt pursuant to the federal regulations is different from non-research activities, such as public health surveillance.*

1. **Date of Application:**
2. **Title of Project:**
3. **Investigator Contact Information:**
4. **Exemption Categories:**

The Revised Common Rule is the set of federal regulations that governs research involving human subjects and can be found at 45 CFR 46. The regulations recognize eight categories of research that are exempt from review by an IRB.

Below, please check off the category that you believe applies to your proposed research. The definitions for each category can be found at [45 CFR 46.104(d)](https://www.ecfr.gov/cgi-bin/text-idx?SID=f7dac07b03f8f4de382d8f2c323a52e2&mc=true&node=sp45.1.46.a&rgn=div6) and may include multiple criteria.

*Please review the definitions at 45 CFR 46.104(d) carefully before submitting this form.*

|  |  |
| --- | --- |
|  | 45 CFR 46.104(1): Certain research in educational settings |
|  | 45 CFR 46.104(2): Research that only involves educational tests, survey procedures, interview procedures, or observation or public behavior |
|  | 45 CFR 46.104(3): Research involving benign behavioral interventions |
|  | 45 CFR 46.104(4): Secondary research using identifiable private information or identifiable biospecimens for which consent is not required |
|  | 45 CFR 46.104(5): Research and demonstration projects conducted, supported, or approved by a federal department or agency designed to study a public benefit or service program |
|  | 45 CFR 46.104(6): Taste and food quality evaluation and consumer acceptance studies |
|  | 45 CFR 46.104(7): Storage/maintenance of identifiable private information or identifiable biospecimens for potential secondary research use for which broad consent is required |
|  | 45 CFR 46.104(8): Research involving the use of identifiable private information or identifiable biospecimens for secondary research use for which broad consent is required |

1. **Research Subjects**

Will this study target individuals from any of the following groups?

Children (people under age 18 who are not legally emancipated)

Individuals who are pregnant

Individuals who are incarcerated (detained in a penal institution, such as a jail or prison)

Non-English speakers

Individuals with impaired decision-making capacity

Individuals who are economically or educationally disadvantaged

None of the above

Is it possible that the study may incidentally include individuals from any of the following groups (i.e.,

membership to one of the following groups is not part of study exclusion criteria)?

Children (people under age 18 who are not legally emancipated)

Individuals who are pregnant

Individuals who are incarcerated (detained in a penal institution, such as a jail or prison)

Non-English speakers

Individuals with impaired decision-making capacity

Individuals who are economically or educationally disadvantaged

None of the above

1. **Description of the project**

Project purpose and rationale:

Description of the research protocol:

**7. Exemption explanation**

Please explain how this project meets the criteria of the exemption categories checked off in Section

4 of this application:

1. **Signatures**

By signing this document, you indicate that you approve this application for review by the DPH IRB.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature of DPH Principal Investigator* *Date*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature of Section Chief*  *Date*

# APPENDIX D: DPH IRB APPLICATION FORM

**NC Division of Public Health**

**Institutional Review Board for the Health and Safety of Human Subjects**

**Guidance for Researchers Completing the DPH IRB Application Form**

1. **Prohibition against beginning research before receiving IRB approval.** Federal regulations prohibit researchers from starting their research activities without first receiving:
   1. A Notice Letter from the DPH IRB documenting that the proposed research has been approved by the DPH IRB;
   2. A Notice Letter from the DPH IRB documenting that, upon review, the DPH IRB determined that the proposed project is not research involving humans subjects under 45 CFR 46.101 or that the proposed project is research that is exempt from IRB review pursuant to 45 CFR 46.104; or
   3. A copy of an executed reliance agreement documenting that the DPH IRB has agreed to rely upon another IRB’s approval of the proposed study or determination that the proposed project is exempt from IRB review pursuant to 45 CFR 46.104.
2. **Exempt research** If the researcher, in consultation with his or her Section Chief and/or Branch Head, believes that his or her research may be exempt from 45 CFR 46.104 or that his or her work is not research (e.g., it is public health practice) then the researcher should complete the DPH IRB Exemption Determination Form (not this Application Form).
3. **Early review by the DPH IRB Chair and DPH IRB Administrator.** DPH researchers are encouraged to involve the DPH IRB Chair and DPH IRB Administrator early in the process of developing their DPH IRB Application. Researchers may submit draft copies of their Application Form to the DPH IRB Chair and DPH IRB Administrator for initial review and feedback. These early copies do not need to be signed by the researcher’s Section Chief.
4. **Deadlines for applications.** Researchers must submit final, signed copies of their DPH IRB Application Forms at least six weeks before the next regular DPH IRB meeting for the proposed project to be reviewed at the next meeting. DPH IRB meeting dates can be obtained by contacting the DPH IRB Administrator or by visiting the DPH Office of Regulatory and Legal Affairs Sharepoint site. Proposed research that is eligible for expedited review shall be reviewed by the DPH IRB Chair on a rolling basis.
5. **Submitting IRB applications before applying for funding.** It is the preference of the DPH IRB Chair and DPH IRB Administrator that, whenever possible, researchers submit their applications for approval *before* applying for funding opportunities.
6. **Research involving external partners.** Research involving investigators at institutions outside DPH may require approval by the other investigators’ institutions. Researchers are responsible for ensuring that their proposed project has been reviewed by the appropriate IRB(s). Researchers who have questions about whether a study may be subject to review by additional IRBs should consult with the DPH IRB Administrator and DPH IRB Chair.

**DPH IRB Application Form**

**1. Date of Application:**

1. **Title of Project:**
2. **Investigator Information**

Name of Principal Investigator:

Division:

Position Title:

Phone Number:

Fax Number:

Email:

Name of Co-Investigator(s):

Division:

Position Title:

Phone Number:

Fax Number:

Email:

\*Please provide the above information for all investigators who will work on this project, including

statisticians, analysts, etc.

1. **Funding Source or Sponsor**

The funding for this project is:

Federal  State  Industry  Foundation

Other (specify):

This project is not funded

Date of application for funding (actual or anticipated):

Dates of proposed funding:

If the project will be funded, is the funding provider expected to receive anything in exchange for the funding (e.g., a report on the study outcomes, a copy of the data collected, etc.)? Please describe:

1. **Research Information**

Name/location of research site:

Will this study target individuals from any of the following groups?

Children (people under age 18 who are not legally emancipated)

Individuals who are pregnant

Individuals who are incarcerated (detained in a penal institution, such as a jail or prison)

Non-English speakers

Individuals with impaired decision-making capacity

Individuals who are economically or educationally disadvantaged

None of the above

Is it possible that the study may incidentally include individuals from any of the following groups (i.e.,

membership to one of the following groups is not part of study exclusion criteria)?

Children (people under age 18 who are not legally emancipated)

Individuals who are pregnant

Individuals who are incarcerated (detained in a penal institution, such as a jail or prison)

Non-English speakers

Individuals with impaired decision-making capacity

Individuals who are economically or educationally disadvantaged

None of the above

1. **Review by other IRBs**

Has this proposal been submitted to another IRB for review?  Yes  No

* If yes, please provide name of IRB:

1. **Responsibilities of researchers**

I affirm that I have read Section 5.0 of the DPH IRB Protocol, titled “Responsibilities of Research

Investigators.” I understand that I should contact the DPH IRB Chair if I have any questions about

my responsibilities under this policy.

I understand that if my project is determined to be human subjects research then, in accordance

with Section 5.0 of the DPH IRB Protocol and federal regulations, I shall be responsible for

promptly reporting unanticipated problems and instances of serious or continuing noncompliance

to both the DPH IRB Chair and DPH IRB Administrator.

I understand that if my project is determined to be human subjects research then I am required to

complete CITI training before beginning any research activities.

I understand that I am prohibited from beginning any research activity related to this project

without first receiving approval from the DPH IRB.

I understand that failure to comply with the requirements of the DPH IRB, the DPH IRB protocol,

the Belmont Report, and the 2018 Revised Common Rule at any time may result in the

disapproval, suspension, or termination of my research.

1. **Conflicts of interest**

Please review the NC DHHS Conflict of Interest policy, available online at the following address: <https://policies.ncdhhs.gov/departmental/policies-manuals/section-iv-general-administration/policies/conflict-of-interest>. Do any of the principal investigators or co-investigators working on this project have potential conflicts of interest that must be disclosed to the DPH IRB?

Yes. Each investigator with a potential conflict of interest has disclosed the potential

conflict(s) in writing in the section below.

* The following investigators are known to have potential conflicts of interest, which are described in detail here:

No. None of the investigators who, at the time of this application, are known to be working

on this project have any potential conflicts of interest.

1. **Description of the project**

Project purpose and rationale:

Description of the research protocol:

Is this project a clinical trial?

Where will the subjects be studied?

Duration of study:

Subjects:

1. Who is being recruited?
2. Number, age, sex of subjects:
3. Inclusion/exclusion criteria:

Does the research involve the use of a survey instrument?  Yes  No

* If yes, please attach a copy and check the appropriate box below.

The final version of the survey instrument is submitted with this application

A draft version of the survey instrument submitted with this application

A copy of any survey instruments used in this project will be submitted at a later date

How will the results of this project be used?

**10. Benefits and risks of harms**

Anticipated benefits to study participants:

Risk of harm to participants: *Note: this section cannot be left blank.*

**11. Costs and remuneration**

Will this study involve any costs for the subjects?  Yes  No

* If yes, please describe:

Will this study involve remuneration for subject participation?  Yes  No

* If yes, please describe:

**12. Informed consent**

How will informed consent be obtained and documented?

Are you requesting a waiver or alteration of informed consent?  Yes  No

* If yes, please explain why this waiver is necessary:

Please describe the plan for the secure storage of signed consent forms:

According to the consent form, in what situations (if any) will researchers be permitted to breach confidentiality of study participants (e.g., when a researcher may be required to make a report according to state law)?

**13. HIPAA authorization**

Will this study require subjects to sign HIPAA authorizations for the release of protected health

information (PHI)?

Yes  No

Are you requesting that the IRB approve a *waiver* of HIPAA authorization for the release of protected health information (PHI)?

Yes  No

* If yes, please explain why this waiver is necessary to the completion of this project*:*

**14. Recruitment materials**

Please describe any materials or methods that will be used to recruit study subjects:

**15. Situations requiring special review**

Does this application need to be reviewed by the Radiation Safety Committee?

Yes  No

Does this application involve recombinant DNA gene therapy?

Yes  No

**16**. **Attachments**

Please attach all survey instruments, recruitment materials, sample consent forms, and participant information for the proposed project.

**17.** **Signatures**

By signing this document, you indicate that you approve this application for review by the DPH IRB.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature of DPH Principal Investigator* *Date*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature of Section Chief*  *Date*

# APPENDIX E: RESEARCH MODIFICATION FORM

**NC Division of Public Health**

**Institutional Review Board for the Health and Safety of Human Subjects**

**Guidance for Researchers Completing the DPH IRB Research Modification Form**

1. **Prohibition against implementing changes to research before receiving IRB approval, unless necessary to eliminate apparent immediate hazards to subjects.** In accordance with the DPH IRB protocol and the Revised Common Rule (45 CFR 46), researchers are prohibited from implementing changes to their study protocol without first submitting a Research Modification Form to the DPH IRB and receiving DPH IRB approval of the proposed change(s), unless the researcher is implementing a change because it is necessary to eliminate an apparent immediate hazard to subjects. Failure to comply with this requirement may result in the suspension or termination of the research. If a researcher implements a change to the research protocol in order to eliminate an apparent immediate hazard to human subjects then the researcher shall promptly notify the DPH IRB Chair and DPH IRB Administrator of the change by email and by phone.
2. **Increase in risk of harm to subjects must be reported immediately.** Researchers are required to immediately report an increased risk of harm to study subjects to the DPH IRB Chair and DPH IRB Administrator by email and by phone. Increased risk of harm means any risk of harm to study subjects that was not previously contemplated in the DPH IRB-approved study and that puts study subjects at greater risk of harm. The DPH IRB Research Modification Form is not the appropriate mechanism by which to notify the DPH IRB Chair and DPH IRB Administrator of this type of change to a research study.
3. **Early review by the DPH IRB Chair and DPH IRB Administrator.** DPH researchers are encouraged to involve the DPH IRB Chair and DPH IRB Administrator early in the process of developing their DPH IRB Research Modification Forms and may submit draft copies of their Research Modification Forms to the DPH IRB Chair and DPH IRB Administrator for initial review and feedback. These early copies do not need to be signed by the researcher’s Section Chief.
4. **Deadlines for submissions.** Researchers must submit a final, signed copy of their DPH IRB Research Modification Forms at least six weeks before the next regular DPH IRB meeting for the proposed project to be reviewed at the next meeting. DPH IRB meeting dates can be obtained by contacting the DPH IRB Administrator or by visiting the DPH Office of Regulatory and Legal Affairs Sharepoint site. Proposed minor changes (as defined in the DPH IRB protocol) that are eligible for expedited review may be reviewed by the DPH IRB Chair on a rolling basis.
5. **Research involving external partners.** Research involving investigators at institutions outside DPH may require approval by the other investigators’ institutions. Researchers are responsible for ensuring that their proposed project has been reviewed by the appropriate IRB(s). Researchers who have questions about whether a study may be subject to review by additional IRBs should consult with the DPH IRB Administrator and DPH IRB Chair.

**DPH IRB Research Modification Form**

Please complete the form below using the information on your most recently approved DPH IRB Application Form. Use the check boxes to indicate whether you are proposing a modification to each section of the form.

**1. Date of Research Modification Form Submission:**

**Date of Last Approval by the DPH IRB:**

1. **Title of Project:**

No change

Change proposed (please describe in detail):

1. **Investigator Information**

Name of Principal Investigator:

Division:

Position Title:

Phone Number:

Fax Number:

Email:

Name of Co-Investigator(s):

Division:

Position Title:

Phone Number:

Fax Number:

Email:

No change

Change proposed (please describe in detail and, if you are proposing to add an investigator, include

his/her contact information):

1. **Funding Source or Sponsor**

The funding for this project is:

Federal  State  Industry  Foundation

Other (specify):

This project is not funded

Date of application for funding (actual or anticipated):

Dates of proposed funding:

If the project will be funded, is the funding provider expected to receive anything in exchange for the funding (e.g., a report on the study outcomes, a copy of the data collected, etc.)? Please describe:

No change

Change proposed (please describe in detail):

1. **Research Information**

Name/location of research site:

Will this study target individuals from any of the following groups?

Children (people under age 18 who are not legally emancipated)

Individuals who are pregnant

Individuals who are incarcerated (detained in a penal institution, such as a jail or prison)

Non-English speakers

Individuals with impaired decision-making capacity

Individuals who are economically or educationally disadvantaged

None of the above

Is it possible that the study may incidentally include individuals from any of the following groups (i.e.,

membership to one of the following groups is not part of study exclusion criteria)?

Children (people under age 18 who are not legally emancipated)

Individuals who are pregnant

Individuals who are incarcerated (detained in a penal institution, such as a jail or prison)

Non-English speakers

Individuals with impaired decision-making capacity

Individuals who are economically or educationally disadvantaged

None of the above

No change

Change proposed (please describe in detail):

1. **Review by Other IRBs**

Has this proposal been submitted to another IRB for review?  Yes  No

* If yes, please provide name of IRB:

No change

Change proposed (please describe in detail):

1. **Responsibilities of Researchers**

I affirm that I have read Section 5.0 of the DPH IRB Protocol, titled “Responsibilities of Research

Investigators.” I understand that I should contact the DPH IRB Chair if I have any questions about

my responsibilities under this policy.

I understand that if my project is determined to be human subjects research then, in accordance

with Section 5.0 of the DPH IRB Protocol and federal regulations, I shall be responsible for

promptly reporting unanticipated problems and instances of serious or continuing noncompliance

to both the DPH IRB Chair and DPH IRB Administrator.

I understand that if my project is determined to be human subjects research then I am required to

complete CITI training before beginning any research activities.

I understand that I am prohibited from beginning any research activity related to this project

without first receiving approval from the DPH IRB.

I understand that failure to comply with the requirements of the DPH IRB, the DPH IRB protocol,

the Belmont Report, and the 2018 Revised Common Rule at

*Note: you cannot make modifications to Section 7: Responsibilities of researchers, as these are*

*conditions upon which approval by the DPH IRB is contingent.*

1. **Conflicts of Interest**

Please review the NC DHHS Conflict of Interest policy, available online at the following address: <https://policies.ncdhhs.gov/departmental/policies-manuals/section-iv-general-administration/policies/conflict-of-interest>. Do any of the principal investigators or co-investigators working on this project have potential conflicts of interest that must be disclosed to the DPH IRB?

☐ Yes. Each investigator with a potential conflict of interest has disclosed the potential

conflict(s) in writing in the section below.

* The following investigators are known to have potential conflicts of interest, which are described in detail here:

☐ No. None of the investigators who, at the time of this application, are known to be working

on this project have any potential conflicts of interest.

No change

Change proposed (please describe in detail):

*Note: if an investigator has a newly-identified and previously undisclosed potential conflict of interest it may be necessary to suspend his or her involvement in the study until an IRB can review the conflict of interest. Please contact the DPH IRB Administrator if you have questions about this.*

1. **Description of the Project**

Project purpose and rationale:

Description of the research protocol:

Is this project a clinical trial?

Where will the subjects be studied?

Duration of study:

Subjects:

1. Who is being recruited?
2. Number, age, sex of subjects:
3. Inclusion/exclusion criteria:

Does the research involve the use of a survey instrument?  Yes  No

* If yes, please attach a copy and check the appropriate box below.

The final version of the survey instrument is submitted with this application

A draft version of the survey instrument submitted with this application

A copy of any survey instruments used in this project will be submitted at a later date

How will the results of this project be used?

No change

Change proposed (please describe in detail):

**10. Benefits and Risks of Harms**

Anticipated benefits to study participants:

No change expected

Change (please describe in detail any decrease or increase in anticipated benefits to study subjects that will result from the modifications proposed):

Risk of harm to participants:

No change expected

Change (please describe in detail any decrease or increase in risk of harm to study subjects that will

result from the modifications proposed):

**11. Costs and Remuneration**

Will this study involve any costs for the subjects?  Yes  No

* If yes, please describe:

Will this study involve remuneration for subject participation?  Yes  No

* If yes, please describe:

No change

Change proposed (please describe in detail):

**12. Informed Consent**

How will informed consent be obtained and documented?

Are you requesting a waiver or alteration of informed consent?  Yes  No

* If yes, please explain why this waiver is necessary:

Please describe the plan for the secure storage of signed consent forms:

According to the consent form, in what situations (if any) will researchers be permitted to breach confidentiality of study participants (e.g., when a researcher may be required to make a report according to state law)?

No change

Change proposed (please describe in detail):

**13. HIPAA Authorization**

Will this study require subjects to sign HIPAA authorizations for the release of protected health

information (PHI)?

Yes  No

Are you requesting that the IRB approve a *waiver* of HIPAA authorization for the release of protected health information (PHI)?

Yes  No

* If yes, please explain why this waiver is necessary to the completion of this project*:*

No change

Change proposed (please describe in detail):

**14. Recruitment materials**

Please describe any materials or methods that will be used to recruit study subjects:

No change

Change proposed (please describe in detail):

**15. Situations Requiring Special Review**

Does this application need to be reviewed by the Radiation Safety Committee?

Yes  No

Does this application involve recombinant DNA gene therapy?

Yes  No

No change

Change proposed (please describe in detail):

**16**. **Attachments**

Please attach all survey instruments, recruitment materials, sample consent forms, and participant information to which you are proposing a modification.

**17.** **Signatures**

By signing this document, you indicate that you approve this form for review by the DPH IRB.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature of DPH Principal Investigator* *Date*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature of Section Chief*  *Date*

# APPENDIX F: RENEWAL APPLICATION FORM

**NC Division of Public Health**

**Institutional Review Board for the Health and Safety of Human Subjects**

**Guidance for Researchers Completing the DPH IRB Research Study Renewal Form**

1. **Prohibition against continuing research activities if IRB approval lapses.** In accordance with the DPH IRB protocol and the Revised Common Rule (45 CFR 46), researchers are prohibited from continuing research activities after the period of DPH IRB approval ends and if the study has not received renewed approval. Failure to comply with this requirement may result in the suspension or termination of the research.
2. **Renewal for research involving external partners.** If this study involves investigators at institutions outside DPH then this study may also be subject to continuing review and approval of renewal by another IRB associated with that external researcher’s institution. Researchers are responsible for ensuring that their project has been reviewed by the appropriate IRB(s). Researchers who have questions about whether a study may be subject to review by additional IRBs should consult with the DPH IRB Administrator and DPH IRB Chair.

**DPH IRB Research Study Renewal Form**

1. **Date of Submission:**
2. **Study Information**

DPH IRB Study #:

Date of Last Approval by DPH IRB:

Approval Expiration Date:

1. **Title of Project:**
2. **DPH Investigators(s)**

Name:

Role:

Email:

Phone:

Name:

Role:

Email:

Phone:

Name:

Role:

Email:

Phone:

1. **Progress Report**

Please describe the progress of the study over the past year and what work you anticipate conducting as part of the study in the upcoming year (including recruitment of new subjects, administration of additional surveys, data analysis, etc.):

Answer the following questions based on information since the study was last approved or renewed:

|  |  |  |
| --- | --- | --- |
| 1. Have there been any modifications approved since the last review?   If yes, please describe: | Yes | No |
| 1. Have any subjects withdrawn voluntarily or been withdrawn from the study?   If yes, please explain: | Yes | No |
| 1. Have there been any findings (e.g., publications) that alter the risk/benefit analysis or otherwise impact the study?   If yes, please explain: | Yes | No |
| 1. Have there been any potential unanticipated problems or adverse events reported to the DPH IRB Chair and DPH IRB Administrator since the last review?   If yes, please provide the date on which the unanticipated problem or adverse event was reported to the DPH IRB Chair and DPH IRB Administrator and the resolution: | Yes | No |
| 1. Has this study been audited by an external sponsor or monitor since the last review?   If yes, please explain: | Yes | No |
| 1. Will research activities related to this study be limited strictly to data analysis during the upcoming approval period (one year)? | Yes | No |
| 1. Will you be enrolling, consenting, or re-consenting subjects during the upcoming approval period (one year)? | Yes | No |

1. **Requested Action**

Renewed study approval:

Study has always involved only analysis of existing data or specimens:

Study will continue as previously approved[[4]](#footnote-4)

Study involves or involved direct interaction or contact with subjects and:

Enrollment of new subjects continues

Enrollment of new subjects closed; interaction/intervention with previously-enrolled

subjects continues

Enrollment of new subjects is closed; direct interaction and contact with subjects is

completed but subsequent monitoring or follow up continues

Enrollment of new subjects is closed; direct interaction and contact with subjects is

completed; the study is in the data analysis-only phase and is expected to remain in the

data analysis-only phase for the entirety of the upcoming approval period of one (1) year

Terminate study:

Research is completed: Any identifiable data or human biological specimens are stored

according to plan approved by the IRB.

Research is completed: All data or human biological specimens are deidentified.

Research is ending because of lack of funding or other (please explain):

1. **Signatures**

By signing this document, you indicate that you approve this form for review by the DPH IRB.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature of DPH Principal Investigator* *Date*

# APPENDIX G: REQUIRED CITI TRAINING

**2020 Division of Public Health Institutional Review Board (DPH IRB)**

**CITI Training Requirements for DPH Researchers**

**Required Modules** (approx. 4-4.5 hours)

|  |  |
| --- | --- |
|  | History and Ethical Principles - SBE (ID: 490) |
|  | Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2) |
|  | Defining Research with Human Subjects - SBE (ID: 491) |
|  | The Federal Regulations - SBE (ID: 502) |
|  | Assessing Risk - SBE (ID: 503) |
|  | Informed Consent - SBE (ID: 504) |
|  | Privacy and Confidentiality - SBE (ID: 505) |
|  | Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680) |
|  | Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928) |
|  | Research and HIPAA Privacy Protections (ID: 14) |
|  | Conflicts of Interest in Human Subjects Research (ID: 17464) |
|  | Public Health Research and Public Health Practice (ID: 17638) |
|  | Ethical Issues in Public Health Research (ID: 17640) |

**Elective Modules** (approx. 1.5 hours)

*Must complete 4 of the 13 elective modules*

|  |  |
| --- | --- |
|  | Cultural Competence in Research (ID: 15166) |
|  | Hot Topics (ID: 487) |
|  | FERPA for Researchers (ID: 17410) |
|  | Consent Tools Used by Researchers (ID: 16944) |
|  | Consent with Subjects Who Do Not Speak English (ID: 17260) |
|  | Research with Decisionally Impaired Subjects (ID: 16610) |
|  | Research with Older Adults (ID: 16502) |
|  | Research with Persons who are Socially or Economically Disadvantaged (ID: 16539) |
|  | Research with Subjects with Physical Disabilities & Impairments (ID: 16657) |
|  | Students in Research (ID: 1321) |
|  | Vulnerable Subjects - Research Involving Workers/Employees (ID: 483) |
|  | Consent and Subject Recruitment Challenges: Remuneration (ID:16881) |
|  | Records-Based Research (ID: 5) |

**Supplemental Modules**

|  |  |
| --- | --- |
|  | Research in Public Elementary and Secondary Schools - SBE (ID: 508) |
|  | International Research - SBE (ID: 509) |
|  | Internet-Based Research - SBE (ID: 510) |
|  | Data and Safety Monitoring in Human Subjects Research (ID:17433) |
|  | Human Subjects Considerations and Big Data Research (ID:19126) |
|  | Mobile Apps and Human Subjects Research |
|  | Overview of the Clinical Trial Agreement (CTA) (ID: 17356) |
|  | Understanding the Terms of the Clinical Trial Agreement (CTA) (ID: 17357) |
|  | Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA) (ID: 17358) |
|  | Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites (ID: 17359) |
|  | Introduction To Community-Engaged Research (ID:16994) |
|  | Introduction to Community-Based Participatory Research (CBPR) (ID: 16995) |
|  | Ethical and Practical Considerations in Community-Engaged Research (CEnR) (ID: 16996) |
|  | Consent and Biobanks and Associated Databases (ID: 17254) |
|  | Consent and Cultural Competence (ID: 17263) |
|  | Informed Consent and Incidental Findings in Research with Human Subjects (ID: 17342) |
|  | Consent and Subject Recruitment Challenges: Therapeutic Misconception (ID:17259) |
|  | Consent in the 21st Century (ID: 17060) |
|  | Disaster and Conflict Research, Part 1: PI Responsibilities (ID: 17384) |
|  | Disaster and Conflict Research, Part 2: Best Practices and Recommendations (ID: 17385) |
|  | Gender and Sexuality Diversity (GSD) in Human Research (ID: 16556) |
|  | Illegal Activities or Undocumented Status in Human Research (ID: 16656) |
|  | Research Involving Subjects at the End of Life (ID: 16658) |
|  | Research with Critically Ill Subjects (ID: 16592) |
|  | FERPA: An Introduction (ID: 17407) |
|  | Informed Consent and Confidentiality in Public Health Research (ID: 17639) |
|  | FERPA for Institutional Review Boards (IRBs) (ID: 17411) |
|  | Introduction to Public Health Research (ID: 17637) |
|  | Genetic Research in Human Populations (ID: 6) |
|  | Research Involving Prisoners (ID: 8) |
|  | Research Involving Children (ID: 9) |

**2020 Division of Public Health Institutional Review Board (DPH IRB)**

**CITI Training Requirements for DPH IRB Members**

**Required Modules** (approx. 7 hours)

|  |  |
| --- | --- |
|  | History and Ethical Principles - SBE (ID: 490) |
|  | Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2) |
|  | The IRB Member Module - "What Every New IRB Member Needs to Know" (ID: 816) |
|  | Conflicts of Interest in Human Subjects Research (ID: 17464) |
|  | Public Health Research and Public Health Practice (ID: 17638) |
|  | Defining Research with Human Subjects - SBE (ID: 491) |
|  | The Federal Regulations - SBE (ID: 502) |
|  | Assessing Risk - SBE (ID: 503) |
|  | Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928) |
|  | Informed Consent - SBE (ID: 504) |
|  | Consent Tools Used by Researchers (ID: 16944) |
|  | Research and HIPAA Privacy Protections (ID: 14) |
|  | Privacy and Confidentiality - SBE (ID: 505) |
|  | Research with Children - SBE (ID: 507) |
|  | Consent with Subjects Who Do Not Speak English (ID: 17260) |
|  | Research with Decisionally Impaired Subjects (ID: 16610) |
|  | Vulnerable Subjects - Research Involving Workers/Employees (ID: 483) |
|  | Research with Persons who are Socially or Economically Disadvantaged (ID: 16539) |
|  | Research with Subjects with Physical Disabilities & Impairments (ID: 16657) |
|  | Ethical Issues in Public Health Research (ID: 17640) |

**Elective Modules** (approx. .5 hours)

*Must complete 2 of the 5 elective modules*

|  |  |
| --- | --- |
|  | Hot Topics (ID: 487) |
|  | Informed Consent and Confidentiality in Public Health Research (ID: 17639) |
|  | Human Subjects Considerations and Big Data Research (ID:19126) |
|  | Consent and Subject Recruitment Challenges: Remuneration (ID:16881) |
|  | FERPA for Institutional Review Boards (IRBs) (ID: 17411) |

**Supplemental Modules**

|  |  |
| --- | --- |
|  | Research in Public Elementary and Secondary Schools - SBE (ID: 508) |
|  | International Research - SBE (ID: 509) |
|  | Internet-Based Research - SBE (ID: 510) |
|  | Data and Safety Monitoring in Human Subjects Research (ID:17433) |
|  | Cultural Competence in Research (ID: 15166) |
|  | Mobile Apps and Human Subjects Research |
|  | Overview of the Clinical Trial Agreement (CTA) (ID: 17356) |
|  | Understanding the Terms of the Clinical Trial Agreement (CTA) (ID: 17357) |
|  | Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA) (ID: 17358) |
|  | Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites (ID: 17359) |
|  | Introduction To Community-Engaged Research (ID:16994) |
|  | Introduction to Community-Based Participatory Research (CBPR) (ID: 16995) |
|  | Ethical and Practical Considerations in Community-Engaged Research (CEnR) (ID: 16996) |
|  | Consent and Biobanks and Associated Databases (ID: 17254) |
|  | Consent and Cultural Competence (ID: 17263) |
|  | Informed Consent and Incidental Findings in Research with Human Subjects (ID: 17342) |
|  | Consent and Subject Recruitment Challenges: Therapeutic Misconception (ID:17259) |
|  | Consent in the 21st Century (ID: 17060) |
|  | Disaster and Conflict Research, Part 1: PI Responsibilities (ID: 17384) |
|  | Disaster and Conflict Research, Part 2: Best Practices and Recommendations (ID: 17385) |
|  | Gender and Sexuality Diversity (GSD) in Human Research (ID: 16556) |
|  | Illegal Activities or Undocumented Status in Human Research (ID: 16656) |
|  | Research Involving Subjects at the End of Life (ID: 16658) |
|  | Research with Critically Ill Subjects (ID: 16592) |
|  | FERPA: An Introduction (ID: 17407) |
|  | FERPA for Researchers (ID: 17410) |
|  | Introduction to Public Health Research (ID: 17637) |
|  | Genetic Research in Human Populations (ID: 6) |
|  | Research with Older Adults (ID: 16502) |
|  | Students in Research (ID: 1321) |
|  | Research Involving Prisoners (ID: 8) |
| 32. | Records-Based Research (ID: 5) |

**2020 Division of Public Health Institutional Review Board (DPH IRB)**

**Special CITI Training Requirements: IRB Chair and IRB Administrator**

CITI Training Requirements for DPH IRB Members (22 courses, approx. 7.5 hours)

+ the following (for 31 courses, approx. 11.5 hours, in total):

|  |  |
| --- | --- |
|  | Role and Responsibilities of an IRB Chair (ID: 15386) |
|  | IRB Chair Meeting Responsibilities (ID: 15387) |
|  | The IRB Chair's Role Outside of the IRB Meeting (ID: 15388) |
|  | External IRB Review (ID: 16711) |
|  | HRPP/IRB Policies and Procedures\* |
|  | Reporting to Federal Agencies\* |
|  | Communicating with Subjects\* |
|  | Internal Quality Assurance and Quality Improvement of HRPP\* |
|  | External Oversight of the HRPP/IRB: Monitoring and Inspections\* |

**\*** modules are part of the separate IRB Administrator course

# APPENDIX H: LAW AND OTHER GUIDANCE

**Federal Regulations**

2018 Revised Common Rule, 45 CFR 46

Available at: <https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl>

Health Insurance Privacy and Portability Act (HIPAA), 45 CFR 160, 162, and 164

Available at: <https://www.ecfr.gov/cgi-bin/text-idx?SID=6727a746637afcfc9a55ac44a6dc0310&mc=true&tpl=/ecfrbrowse/Title45/45tab_02.tpl>

**Ethics Guiding Documents**

The Belmont Report

Available at: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

**Other Guidance**

Office for Human Research Protections (OHRP)

Available at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html>

1. “Minor change” is not defined in the Revised Common Rule. This definition was developed from guidance and recommendations issued by the HHS Secretary’s Advisory Committee on Human Research Protections, available at: <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-october-13-letter-attachment-b/index.html>. [↑](#footnote-ref-1)
2. “Unanticipated problem involving risks to human subjects or others” is not defined in the Revised Common Rule. This definition was developed using guidance issued by OHRP, which is available at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q1>. [↑](#footnote-ref-2)
3. The Revised Common Rule does not define what it means for research to *involve* human subjects; however, OHRP has issued guidance on the topic in the form of a decision-making flow chart, which is available at: <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c1>. [↑](#footnote-ref-3)
4. If you wish to make changes to the previously approved study protocol please complete and submit a DPH IRB Request for Study Modification Form. In accordance with federal regulations and the DPH IRB Protocol, investigators are prohibited from making changes to their research study without first obtaining approval by the IRB, unless the changes are necessary to prevent apparent immediate hazard to subjects. [↑](#footnote-ref-4)