POLICIES AND PROCEDURES FOR THE PROTECTION OF HUMAN SUBJECTS FOR

Division of Human Research Compliance
Policy, Legislative Affairs and Analytics Division
8004 Franklin Farms Drive
Richmond, Virginia 23229
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Kathryn A. Hayfield, Commissioner
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ACKNOWLEDGMENTS

In this edition, we incorporate both the federal regulations as well as state regulations governing the protection of human subjects participating in federally funded or sponsored research to include the changes to the "Common Rule" implemented January 2019.

Please submit Human Research Review Committee (HRRC) applications to:

Devin Bowers
HRRC Co-Chair and Administrator
Policy, Legislative Affairs and Analytics
Virginia Department for Aging and Rehabilitative Services
8004 Franklin Farms Drive
Richmond, Virginia 23229
(804) 662-7010
Email: devin.bowers@dars.virginia.gov

or

Catherine Harrison
HRRC Chair
Policy, Legislative Affairs and Analytics Director
Virginia Department for Aging and Rehabilitative Services
8004 Franklin Farms Drive
Richmond, Virginia 23229
Phone: (804) 662-9968
Email: catherine.harrison@dars.virginia.gov
Toll Free: 1-800-552-5019
TTY Toll Free: 800-464-9950
FAX (804) 662-7663

For questions or comments about this manual or compliance concerns please contact:

Catherine Harrison
HRRC Chair
Policy, Legislative Affairs and Analytics Director
Virginia Department for Aging and Rehabilitative Services
8004 Franklin Farms Drive
Richmond, Virginia 23229
Phone: (804) 662-9968
Email: catherine.harrison@dars.virginia.gov
Toll Free: 1-800-552-5019
TTY Toll Free: 800-464-9950
FAX (804) 662-7663

DARS HUMAN RESEARCH AND REVIEW COMMITTEE
POLICIES, PROCEDURES AND GUIDANCE MANUAL

Background

I. Overview

Title 45 Part 46 of the US Code of Federal Regulations (CFR) – Protection of Human Subjects establishes the application of *Belmont Report* principles and provides the process necessary to protect the rights of human subjects involved in research. Federal funds may not be expended for research involving human subjects unless the requirements of *Title 45 Part 46* have been satisfied (§46.122). To eliminate confusion and promote uniformity, a number of federal departments and agencies have adopted as regulation a common Federal Policy for the Protection of Human Research Subjects (*Common Rule*).

One of the programs that the Virginia Department of Aging and Rehabilitative Services (DARS) operates is the vocational rehabilitation (VR) program that receives funding and oversight from the Rehabilitation Services Administration, Office of Special Education and Rehabilitative Services, US Department of Education (DOE). DOE has codified the *same requirements found in the Common Rule* (Federal Policy for the Protection of Human Research Subjects) at 34 CFR Part 97. Several other DARS programs are administered under the federal Administration for Community Living (ACL), which is in the US Department of Health and Human Services Secretariat (DHHS) and fall under the auspices of the Common Rule.

The DHHS regulations incorporate the *Common Rule* as Subpart A of 45 CFR 46. Additionally, DOE has adopted Subpart D of 45 CFR 46, *Protections for Children Who Are Subjects in Research*. Therefore, all federally funded or sponsored human subjects research involving minors must comply with both Subpart A and Subpart D of 45 CFR Part 46.

For the purposes of this policy and procedures document, the term ""covered entity" includes all DARS' divisions, programs, and offices (except for the Division of Disability Determination Services); Centers for Independent Living; sheltered workshops (i.e., employment services organizations with contracts or vendor arrangements with DARS), Area Agencies on Aging; and the Wilson Workforce and Rehabilitation Center (WWRC). DDS is fully funded by the US Social Security Administration (SSA). Any research involving DDS employees, clients and/or personally identifiable data, must be approved by SSA.

Research that has been approved by the Human Research Review Committee (HRRC) may be subject to further appropriate review and approval or disapproval by the DARS Commissioner. However, the Commissioner shall not approve the research if it has not been approved by the HRRC (45 CFR § 46.112).

Covered entities shall comply with pertinent federal, state laws or regulations which provide additional protections for human subjects (45 CFR § 46.101(e)). In the case of any discrepancy between state laws or regulations, or DARS policies and procedures and current federal regulations, and policies for the conduct of human subject research, the federal requirements take precedence.

This document fulfills terms of DARS's Federal Wide Assurance (FWA) on file with the DHHS to have written procedures for the conduct of human subject research.

The FWA is a binding written agreement between DARS and DHHS, which states that DARS is guided by the ethical principles of the *Belmont Report* and will comply with federal regulations (45 CFR Part 46) for federally-funded human subject's research.

Non-federally funded research activities conducted by covered entities shall be conducted in compliance with Sections 32.1-162.16 et seq. and 51.5-132 of the Code of Virginia, which is the basis for DARS regulations (22VAC30-40-10 et seq.), and this policy and procedures document.

Non-therapeutic research is prohibited unless the HRRC determines that such research will not present greater than minimal risk to the subject (§ 32.1-162.19 of the Code of Virginia and 22VAC30-40-40 C).

This policy and procedures document is intended to be an electronic resource. Please refer to the electronic version of this document to ensure that you are using the most recently updated version. The signature copy of this document is maintained by the DARS Policy, Legislative Affairs and Analytics Division. An electronic copy of this document can be obtained from the HRRC webpage.

To report possible areas or incidences of research non-compliance with federal or state laws and regulations which involve covered entities, please contact the DARS HHRC Chair in Policy, Legislative Affairs and Analytics.

II. Statement of Principles

In accordance with § 51.5-132 of the Code of Virginia and ensuing regulations, DARS is responsible for safeguarding the rights and welfare of human subjects who volunteer to participate in human subject research conducted by covered entities. As such, DARS assures that no human subject research will be conducted or authorized by covered entities unless the DARS HRRC has reviewed and approved such research.

The National Research Act of 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1979, the Commission published its report, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, commonly called the *Belmont Report*. Today's federal regulations for the protection of human subjects are based on the ethical principles of the *Belmont Report*. The *Belmont Report*

identifies three basic principles as particularly relevant to the ethics of research involving human subjects:

(1) Respect for Persons,
(2) Beneficence, and
(3) Justice.

DARS assures that all human subjects' research will comply with the terms of its Federal-wide Assurance (FWA).

III. Legal Authority

The DARS HRRC is authorized to review and approve proposed research conducted or authorized by covered entities as directed by:

i. 45 CFR Part 46 Protection of Human Subjects;
ii. 34 CFR Part 97, as applicable;
iii. Code of Virginia §§ 32.1-162.16 et seq. and 51.5-132;
iv. 22 VAC 30-40-10 et seq. Protections of Participants in Human Research; and
v. This document, the Policies and Procedures for the Protection of Human Subjects.

IV. HRRC Mission and Purpose

The purpose of the HRRC is to ensure that human research involving covered entities maintains an individual's rights to privacy and protection from harm or risk. The HRRC reviews research proposals and requests to determine how federal and state human research subject laws and regulations apply to proposed research activities. The HRRC conducts competent, complete, and professional review of human research activities conducted or authorized by covered entities to ensure the privacy and protection of human subject participants.

V. Definitions

The following terms have the following meanings:

"Covered entity" means the Department for Aging and Rehabilitative Services, the Wilson Workforce and Rehabilitation Center, area agencies on aging, sheltered workshops, or independent living centers.

"Human subject" means "a living individual about whom an investigator (whether professional or student) conducting research obtains:

i. data through intervention or interaction with the individual, or
ii. identifiable private information."

For the purposes of this policy and procedures document, the term "**subject**" means any and all subjects and/or participants involved in the research project.
"**Identifiable private information**" means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

"**Informed consent**" means a process by which the investigator fully explains the research activities and ensures that the prospective subject has sufficient opportunity to ask questions and has sufficient time to make a decision whether or not to participate in the research prior to signing the HRRC-approved written consent document. Informed consent shall be prospectively obtained without coercion and in accordance with 22VAC30-40-100.

"Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

"Interaction" includes communication or interpersonal contact between investigator and subject.

"**Minimal risk**" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"**Nontherapeutic research**" means human subject research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the subject.

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) to constitute research involving human subjects.

"Research" means "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

The Human Research Review Committee (HRRC) Membership

I. Appointments

The DARS Commissioner shall be responsible for appointing members to the HRRC. Term of membership commences with the date of the appointment letter and may be unlimited. To review the current committee membership please visit the HRRC webpage.

II. Composition

A. Primary Members

As set forth in 45 CFR §46.107, the HRRC shall have at least five members. Members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The HRRC shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the HRRC shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The HRRC shall, therefore, include persons knowledgeable in these areas.

Since this HRRC regularly reviews research that involves a vulnerable category (45 CFR §46.107) of subjects, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

At least two members of the HRRC must be individuals whose primary concerns are in non-scientific or ethical areas (e.g., members of the clergy, lawyers).

B. Alternate Members

To maintain the HRRC size, alternate members may be appointed to review a project where a member has a conflicting interest or when a primary member cannot attend the meeting. Alternate members are subject to the same requirements as members, including the conflict of interest and confidentially requirements. Alternate members may attend the HRRC, count towards a meeting quorum, and vote in place of any absent primary voting member.

C. Ad Hoc Reviewers

The HRRC may invite individuals with special expertise ("ad hoc reviewers") to assist in the review of research protocols. They may be from within a covered entity or external to a covered entity/entities. Ad hoc reviewers are subject to the conflict of interest and confidentially requirements for all proposal reviews. Ad hoc reviewers cannot vote on the HRRC.

III. Member Responsibilities

Members are expected to:

- Attend the required initial education program.
- Maintain confidentiality of all HRRC-related activities and refrain from discussing them outside the context of these duties.
- Conduct competent, complete and professional reviews of research protocols in a timely manner.
- Attend and contribute to the HRRC review and discussion of protocols during full committee meetings.
- Attend any required continuing education for HRRC members. Adhere to the conflict of interest policy.

IV. Officers

Officer positions shall include the Chair and the Co-Chair/HRRC Administrator. The Chair shall be the Director of the DARS Policy, Legislative Affairs and Analytics Division. The Co-Chair/Administrator shall be designated by the Chair, and shall be an employee of DARS.

V. Conflicts of Interest

No member of the HRRC shall be directly involved in the proposed human research project or have administrative approval authority over the proposed research, except in connection with her/his responsibilities as a member of the HRRC. No member shall participate in an initial or continuing review of any project in which they have a conflicting interest. The HRRC is responsible for determining whether a member has a conflict of interest.

Members must complete and sign the Conflict of Interest HRRC Member Statement (Form A) to acknowledge receipt of the conflict of interest policy. The HRRC Administrator shall keep the signed Conflict of Interest HRRC Member Statement (Form A) on file.

HRRC Operations

For review by the HRRC, a covered entity's research project or activity must meet both of the definitions for "research" and "human subject." If it does not, then the covered entity does not need to submit it to the HRRC. Questions as to whether or not activities constitute human subjects research may be directed to the Chair or the Co-Chair/Administrator of the HRRC.

Please refer to appendices for additional information regarding the steps to determine whether activities constitute human subjects research.

I. Full Committee Meetings

The HRRC Committee will convene at least once annually for research requiring continuing review and will convene more often as needed. Individual meetings may be scheduled if an application requiring Full Committee review is necessitated.

Meetings may be cancelled by the Chair due to: (a) insufficient applications requiring Full Committee review, (b) inability to secure a quorum for attendance, or (c) other reasons (e.g., inclement weather) that make a scheduled meeting unnecessary.

The HRRC Co-Chair/Administrative will distribute information on the time and place of all HRRC meetings and study materials for HRRC member review prior to all meetings.

II. Electronic Meetings

The Federal Office for Human Research Protections (OHRP) in the DHHS recognizes HRRC meetings that are conducted electronically provided that:

1. Each participating member has received all pertinent materials prior to the meeting, and can actively and equally participate in the discussion of all research projects;
2. Minutes of such meetings clearly document that these conditions have been satisfied in addition to the usual HRRC meeting documentation requirements;
3. The HRRC follows its written procedures; and
4. Except when an Exempt, Expedited or Limited Review, or Cooperative Research procedure is used, review of proposed research must be done during convened Full Committee meetings at which a majority of the members of the HRRC are in attendance.

When appropriate, all virtual meetings must be conducted in a secure manner.

III. Meeting Agendas

Agendas must include each research project by HRRC control number, Principal Investigator name, and title of research project. Agendas must be included in the official record to assist with the specifics of an item or submission.

A copy of the final agenda may be placed with the minutes in order to assist in the location of items within the minutes. The agenda is not considered a required document as per regulation, but rather a tool for organizing meetings and preparation of minutes.

IV. Conduct of Business

Prior to convening an HRRC meeting or prior to any review of a research project, HRRC members, including alternates, must have the following forms signed and on file with the Co-Chair/HRRC Administrator:

- Conflict of Interest HRRC Member Statement (Form A)
- HRRC Confidentiality Agreement (Form B)

A. Order/Quorum

The HRRC meeting is called to order by the Chair when a quorum of members is in attendance. The meeting ends or is suspended whenever a quorum of members is no longer present for deliberations. A quorum is required to review research and vote.

A quorum requires a majority of the voting members. For project review purposes, a quorum will consist of a simple majority of the HRRC members, including at least one HRRC member whose primary expertise is considered to be nonscientific in nature.

With approval from the Chair, designated alternate members may serve in the place of regular members, count toward a quorum, and vote if materials were presented to them in advance of the meeting.

B. Attendees and Guests

At the discretion of the Chair and/or primary reviewer, the Principal Investigator (PI) may be invited to attend the meeting for the purpose of additional clarification or discussion. A Guest Attendance Certification (Form C) must be completed by the attendee, and signed by both the attendee and a witness. Investigator(s) is (are) required to leave the meeting for subsequent discussion and voting.

Persons may be permitted to observe HRRC meetings as guests under the following conditions:

1. Guest attendance is at the discretion of the Chair;

2. Guests may be asked to leave at any time;
3. Guests must not be in attendance during the review of research in which they serve as PI or Co-Investigator;
4. Guests may be asked to sign a HRRC Confidentiality Agreement (Form B);
5. Guests must sign a Conflict of Interest Disclosure Statement (Form D) and reveal any conflicts of interest prior to attendance, and/or must excuse themselves if a potential conflict reveals itself; and
    a. If applicable, Form D will need to be accompanied by Listing of Co-Investigators (Form E).
6. Guests must sign in and may be asked to document the purpose of their visit.

C. Voting and Actions

Only members and alternate members may vote. Votes by proxy are not allowed. At the discretion of the Chair, voting may be by written ballot or show of hands.

A vote regarding a project must follow a motion proposed by a voting member of the HRRC. A second member of the HRRC must second the motion. The Chair will call for a vote if no further discussion is raised. In order for research to be approved by the HRRC, it must receive the approval of a majority of those members present at a meeting in which a quorum exists.

No member may vote who has a conflict of interest with respect to the research under consideration.

During a convened meeting of the HRRC, any member may make a motion using one of the following procedures:

1. Approved: Defined as approved as is, with no further action requested or required.
2. Approved on condition: Defined as approved on condition that scripted changes are made to documents and returned for verification via expedited review, not returned to the Full Committee. This action cannot be used at the time of continuing review.
3. Tabled: Defined as the requirement that additional information must be provided and/or more than scripted changes to documents must be made and returned to the Full Committee for further review. This action cannot be used at the time of continuing review.
4. Disapproved: Defined as not approved by the HRRC for reasons specified in a Letter of Disapproval.
5. Suspended: Defined as the suspension of approval of the research project for any reason the HRRC deems appropriate.
6. Termination: Defined as the termination of approval of the research project for any reason the HRRC deems appropriate.
7. Approved/Short Term-A: This may only be used for continuing reviews. This action allows for continuing review to proceed to approval where scripted changes have been requested by the HRRC, a delay in implementing the changes will not place subjects at

increased risk of harm, and the HRRC will not have time to approve the changes before HRRC approval expires. All scripted changes to documents must be made and returned for verification via expedited review as detailed in the approval letter. Under this motion to approve, expiration of approval is on the last day of the second month from the HRRC meeting (e.g. HRRC meeting date is June 1, 2019 and approval will expire August 31, 2019). Once the supplemental information/modifications (scripted only) have been made and are verified by expedited review, the continuing review cycle will be reset (not to exceed one year from full committee continuing review). The HRRC is using this process at the time of continuing review in order to ensure that scripted changes requested by HRRC members are given valid and thorough consideration, and not overlooked simply due to concerns about the impact of an interruption in HRRC approval.

8. Approved/Short Term-B: This may only be used for continuing reviews. This action allows continuing review to proceed to approval where supplemental information or non-scripted changes have been requested by the HRRC, a delay in reviewing the information or implementing the changes will not place subjects at increased risk of harm, and the HRRC will not have time to approve the changes before HRRC approval expires. The HRRC is using this process at the time of continuing review in order to ensure that supplemental information or non-scripted changes requested by HRRC members are given valid and thorough consideration, and not overlooked.

D. Meeting Minutes

The official meeting minutes shall include a record, without individual identification, of the number of votes to approve, disapprove, table, or abstain regarding all actions. In the event a member of the HRRC elects to abstain, the minutes should record the abstention and the identity of the individual who did not vote.

V. HRRC Record Retention

The Co-Chair/Administrator maintains all required records for individual studies until at least three years past the end date of the study, or longer if required by regulations.

The Co-Chair/Administrator also maintains all records of HRRC meetings in accordance with records laws and federal regulations.

The Co-Chair/Administrator maintains and updates the HRRC website as needed, creates and updates the policy manual and forms, and publishes and disseminates important communications to the HRRC and Principal Investigators with approved and pending research projects.

A. Virginia Freedom of Information Act and Institutional Review Boards

An opinion published by the Virginia Office of the Attorney General indicates Institutional Review Boards (IRB) are exempt from the Freedom of Information Act (FOIA). The opinion states that IRB are not public bodies; therefore, they are not subject to the provisions of FOIA. Records are not subject to the inspection or copying of any citizen.

HRRC Reviews and Decision Making Process

I. Background

The HRRC (or designated reviewers, in the case of exempt and expedited or limited reviews) is required by state regulations to review all requests within 45 calendar days after submission of a complete application.

The HRRC shall review and have authority to approve and require modifications in (to secure approval), or disapprove all research activities covered by this policy (45 CFR § 46.109). All requirements in this process must be fulfilled.

No human research shall be conducted or authorized by a covered entity unless the DARS HRRC, or designated reviewer as appropriate, has reviewed and approved the proposed human research project.

II. Applications and Submission Materials

The HRRC Chair or Co-Chair/Administrator will screen all applications for completeness. When an application is submitted but is not complete, the HRRC Chair or Co-Chair/Administrator shall make reasonable attempts to obtain the missing information. Only complete applications will be advanced for review and approval by the HRRC.

Upon receipt of a new research project submission, the HRRC Chair or Co-Chair/Administrator conducts an initial review, called a “pre-review” using the Pre-Review Checklist (Form F). The HRRC Chair or Co-Chair/Administrator determines the review level required (Exempt, Expedited or Limited, Full HRRC, Cooperative Research, or Not Human Subjects Research). Depending on the review level and completeness of the submission, HRRC Chair or Co-Chair/Administrator may either request revisions or process the submission to the next stage of review.

Research records must be kept for a minimum of three years after completion of the study. Each Principal Investigator must retain records of all correspondence relating to the use of human subjects in research, as required by the HRRC and federal regulations. As applicable, this includes:

1. All HRRC application materials (initial, amendment, continuing review, etc.);

2. All approval letters and important correspondence (initial, continuing review, and amendment approval letters; reportable event memos, etc.);
3. All versions of approved informed consent forms;
4. Training records for research team members; and
5. Research data, which must be stored according to the HRRC approved protocol.

III. Key Determinations for Review of Human Subjects Research

In order to approve a new research protocol involving human subjects, the HRRC must determine that all of the criteria from 45 CFR § 46.111 are satisfactorily met.

To approve a research protocol, the HRRC must consider and approve all criteria below:

1. The proposed research design is scientifically sound and will not unnecessarily expose subjects to risk;
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result;
3. Subject selection is equitable;
4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence;
5. Informed consent is obtained from research subjects or their legally authorized representative(s);
6. Risks to subjects are minimized; and
7. Subject privacy and confidentiality are maximized.

To assist with understanding the research review requirements and the HRRC approval process, please consider reviewing the Decision Process Flowcharts found here.

A. Is the Project Considered Research?

Research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities" [45 CFR 46.102(d) & 22 VAC 30-40-10].

Systematic means "characterized by order and planning; not haphazard; a series of orderly actions."

General knowledge is synonymous with generalizable knowledge which means that the intent of collecting the information is to learn and apply what is discovered to a wider group of individuals than those included in the study and to publish the results in an outside publication such as a journal, trade magazine, conference proceedings, or periodical.

The Quality Improvement Determination Worksheet (Form G) may be useful in considering this question.

B. Does the Project Involve Human Subjects?

Human research means "any systematic investigation which utilizes human participants who may be exposed to physical or psychological injury as a consequence of participation and which departs from the application of established and accepted therapeutic methods appropriate to meet the participant's needs."

Human participant means "a living individual about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction with the individual or (ii) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or participant's environment that are performed for research purposes."

C. Does the Project Qualify for Exempt Review?

Unless they are covered by some other provision, the following kinds of research are exempt from full HRRC review:

Category 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to impact adversely student opportunity to learn required educational content or the assessment of educators who provide instruction, such as:

a. Research on regular and special education instructional strategies; or
b. Research on the effectiveness of or the comparison among instructional techniques, curriculum, or classroom management methods.

Category 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), unless:

a. The information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and the HRRC conducts a limited review to make the determination required by 22VAC30-40-70 J 7; or
b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

Category 3. Research involving benign behavioral interventions.

a. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses, including data entry, or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
    i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the HRRC conducts a limited review to make the determination required by 22VAC30-40-70 J 7.

b. For the purpose of this subsection, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all of these criteria are met, examples of benign behavioral interventions include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

c. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless a subject authorizes the deception through a prospective agreement to participate in research in circumstances in which a subject is informed that he will be unaware of or misled regarding the nature or purposes of the research.

Category 4. Secondary research for which consent is not required: Secondary research using identifiable private information, if at least one of the following criteria is met:

a. The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available;

b. The information is recorded by the investigator in a manner that subjects (i) cannot be identified, directly or through identifiers linked to the subjects; (ii) the investigator does not contact the subjects; and (iii) the investigator will not re-identify the subject;

c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR Part 160, General Administrative Requirements, and Part 164, Security and Privacy, Subparts A and E, for the purposes of "health care operations'' or "research'' as those

terms are defined at 45 CFR 164.501 or for "public health activities and purposes'' as described under 45 CFR 164.512(b); or

d. The research is conducted by, or on behalf of, the department using department-generated or department-collected information obtained for nonresearch activities if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with § 208(b) of the E-Government Act of 2002, 44 USC § 3501 note; if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 USC § 552a; and if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 USC § 3501 et seq.

Category 5. Research and demonstration projects conducted by or subject to the approval of the commissioner, which are designed to study, evaluate, or otherwise examine:

a. Public benefit or service programs;
b. Procedures for obtaining benefits or services under those programs;
d. Possible changes in or alternatives to those programs or procedures; or
e. Possible changes in methods or levels of payment for benefits or services under those programs.

Category 6. Taste and food quality evaluation and consumer acceptance studies:

a. If wholesome foods without additives are consumed; or
b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

Category 7. Storage or maintenance for secondary research for which broad consent is required. Storage or maintenance of identifiable private information for potential secondary research use if the HRRC conducts a limited review and makes the determinations required by 22VAC30-40-70 J 8.

Category 8. Secondary research for which broad consent is required: Research involving the use of identifiable private information, if it meets the following criteria:

a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information is obtained in accordance with 22VAC30-40-100 A and D;
b. Documentation of informed consent or waiver of documentation of consent is obtained in accordance with 22VAC30-40-100 L;

c. The HRRC conducts a limited review and makes the determination required by 22VAC30-40-70 J 7 and makes the determination that the research to be conducted is within the scope of the broad consent referenced in subdivision 1 of this subsection; and
d. The investigator does not include returning individual research results to subjects as part of the study plan. The investigator shall not be prevented from abiding by any legal requirements to return individual research results.

For more information on exempt review, please refer to IV. Types of Reviews, A. Exempt Reviews.

D. Does the Project Qualify for Expedited or Limited Review?

Expedited or limited review procedures may apply for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

The HRRC may use the expedited or limited procedure for categories of research that are listed in 63 FR 60364-60367 where one or more of the following apply:

1. Some or all of the research appearing on the list and found by the reviewer to involve no more than minimal risk.
2. Minor changes in previously approved research during the period of one year or less for which approval is authorized; or
3. Research for which limited review is a condition of exemption under 22VAC30-40-80 2 c, 22VAC30-40-80 3a (1), and 22VAC30-40-80 7 and 8.

For more information on expedited review, please refer to IV. Types of Reviews, B. Expedited and Limited Reviews.

E. Minimal Risk

The regulations state that “minimal risk” means “that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR 46.102(i)).

Examples of minimal risk are:

1. Study poses no more risk than expected in daily life (e.g., blood draw, physical exam, routine psychological testing);
2. Non-interventional studies (e.g., observational studies of behavior or nutrition);
3. Survey/Questionnaire studies of a non-sensitive nature;
4. Electrophysiological studies in healthy subjects or clinical populations (surface recordings such as EEG, ERP, MEG);
5. Genomic studies;

6. Non-invasive imaging (e.g., MRI and fMRI) in healthy subjects or clinical populations to investigate basic mechanisms of brain function;
7. Research involving materials (data, documents, records—including medical records—or biological specimens) that have been collected or will be collected solely for research purposes;
8. Survey/interview research where disclosure of the information would not place the subjects at risk or be damaging to them or their reputation in any way.

Examples of greater than minimal risk are:

1. Studies involving identification of the subjects and/or their responses which would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk;
2. Studies involving deception; and
3. Manipulation of subjects' emotions.

Research involving minimal risk that fits into one or more exempt or expedited or limited review categories may be reviewed by a designated HRRC Chair, Co-Chair/Administrator or other designated reviewer rather than by the full HRRC.

F. Additional Protections and Special Considerations

The HRRC considers certain groups of human subjects to be particularly vulnerable in a research setting. The HRRC considers additional protections for research activities involving children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

In reviewing these research projects, the HRRC ascertains that the inclusion of the vulnerable population is adequately justified and that additional safeguards are implemented to minimize risks unique to each population. The HRRC considers for approval, research projects involving vulnerable populations if one of the following conditions is met:

1. The research does not involve more than minimal risk to the subject;
2. the research is likely to benefit the subject directly, even if the risks are considered to be more than minimal; or
3. the research involves greater than minimal risk with no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.

G. Informed Consent

The HRRC shall require documentation of informed consent or may waive documentation in accordance with this section.

Depending on the type of review and the research project, the HRRC may require additional elements of informed consent, waive or alter elements of the informed consent, or allow for broad consent when in the HRRC's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects. For those projects requesting to waive informed consent, principal investigators should complete the Waiver of Informed Consent Request (Form H).

Requirements for informed consent for research projects are governed by 45 CFR 46.116 and 22VAC30-40-100.

In seeking informed consent, the following basic elements shall be provided to each prospective human subject or prospective human subject's legally authorized representative:

1. A statement that the project involves research, an explanation of the purposes of the research and the expected duration of the human subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the human subject;
3. A description of any benefits to the human subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the human subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the human subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of who to contact for answers to pertinent questions about the research and the human subject's rights, and who to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the human subject is otherwise entitled, and the human subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about research that involves the collection of identifiable private information:
    a. A statement that identifiers may be removed from the identifiable private information and that, after such removal, the information could be used for

future research studies or distributed to another investigator for future research studies without additional informed consent from the human subject or the human subject's legally authorized representative, if this may be a possibility; or

b. A statement that the human subject's information collected as part of the research, even if identifiers are removed, shall not be used or distributed for future research studies.

Notwithstanding consent by a legally authorized representative, no person shall be forced to participate in any human subject research. Further, no legally authorized representative may consent to nontherapeutic research unless the HRRC determines that such nontherapeutic research will present no more than a minor increase in overall risk to the prospective subject. No nontherapeutic research shall be performed without the consent of the human subject.

The HRRC has the authority to observe or have a third party observe the consent process and research at any time.

H. Researcher Conflicts of Interest

The HRRC has the responsibility to ensure that these potential conflicts of interest do not negatively impact the rights or welfare of participants, or the fair and unbiased review of research proposals.

In each research project review, the HRRC notes any potential conflict of interest that could impact the rights or welfare of participants, and may require additional safeguards to minimize this impact.

For research involving entities for which the Principal Investigator has a financial conflict of interest disclosed to the HRRC, the Principal Investigator must have a conflict management plan that is submitted to the HRRC for review.

For each project, the principal investigator is required to complete and submit the Conflict of Interest Disclosure Statement (Form D) to the HRRC.

I. Recruitment Materials

Recruitment also requires HRRC oversight.

Materials developed for recruiting human participants for research activities must be reviewed and approved by the HRRC. It is recommended that the materials used in recruitment include the HRRC research project number and HRRC approval date.

The materials should be submitted with all formatting, pictures, etc. included. The HRRC evaluates not only the written content, but the overall presentation for appropriateness and to ensure the recruitment material does not unduly promote compensation or promise benefit.

IV. Types of Reviews

There are four types of reviews:

- Exempt,
- Expedited or Limited,
- Full HRRC, and
- Cooperative Research.

The DARS Commissioner may restrict, suspend, terminate, or choose not to authorize the HRRC's use of the exempt and expedited or limited review procedures.

A. Exempt Review

Certain types of research projects may be eligible for review under exempt review procedures. The research must involve no more than minimal risk and fit one or more of the categories for exempt research as outlined in 45 CFR § 46.104(d) and 22VAC30-40-80.

The Chair or Co-Chair/Administrator will review the research project and may assign an HRRC member as an additional reviewer, if needed. The Chair or Co-Chair/Administrator will review the exempt research application and all supporting materials to determine whether the research meets the criteria of one or more of the eligible categories.

The Co-Chair/Administrator will notify the Principal Investigator of the outcome of the review in writing. All HRRC decisions regarding approval, disapproval, or request for revisions will be communicated to the Principal Investigator in writing within 15 business days following receipt of a completed submission. The reviewer's determination is documented in Review Criteria Checklist (Form I).

For a complete listing of the required documents for an application for exempt review, please review the Exempt Review Application Checklist (Form J).

B. Expedited and Limited Reviews

1. Expedited Review:

Certain types of research protocols may be eligible for review under expedited review procedures as governed by 45 CFR § 46.110 and 22VAC30-40-90. The research must involve no more than minimal risk and fit one or more of the categories for expedited review procedures as specified in the Federal Register.

The Co-Chair/Administrator completes an initial review of the study submission and will assign one or more reviewers from among the HRRC members, in consultation with the Chair when

needed. HRRC members are assigned to review research protocols based on the nature of the research and the expertise of the HRRC member.

The Co-Chair/Administrator may act as the sole reviewer if they feel they have adequate expertise to complete the review without input from additional reviewers. Examples: research involving only records review, or where study procedures involve extremely low or no risk.

Assigned HRRC members will review the research application and all supporting materials to determine whether the research:

1. Meets the definition of minimal risk,
2. Meets the criteria of one or more of the eligible categories, and
3. Fulfills the regulatory criteria for approval.

HRRC members reviewing a study may:

1. Ask questions about the research,
2. Require modifications to the protocol and other study materials,
3. Recommend approval,
4. Request additional HRRC members to review the protocol, or
5. Request that the study be reviewed by the full board.

2. Limited Review:

Limited review is a process that is required only for certain exemptions, and does not require an HRRC to consider all of the HRRC approval criteria in 45 CFR § 46.111. In a limited review, the HRRC must determine that certain conditions, which are specified in 45 CFR Part 46, are met.

Limited review may be done via the Expedited Review mechanism, that is, by the Chair or an experienced HRRC member designated by the Chair, however, it may also be conducted by the full HRRC.

The purpose of limited review is to ensure privacy and confidentiality protections are in place with exempt research that involves the collection or use of sensitive, identifiable data and when "broad consent" was obtained and (if appropriate) documented according to an approved protocol. There are four Exemptions that may require limited review:

1. Research that only includes interactions involving educational tests, survey or interview procedures, or observation of public behavior if at least one of the three provisions included in this exemption is met. Limited review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. For this exemption, the limited review serves to

determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

2. Research involving benign behavioral interventions in conjunction with specified data collection methods if the criteria listed in one of three possible provisions are met. Limited review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers. For this exemption, the limited review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
3. Storage and maintenance of identifiable private information for potential secondary research use, for which broad consent is required. This exemption requires limited review to determine that the requirements for broad consent are met; that broad consent is appropriately documented or documentation of broad consent is appropriately waived; and that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, if there will be a change made for research purposes in the way the identifiable private information are stored or maintained.
4. Secondary research involving identifiable private information for which broad consent is required. This exemption requires the HRRC to determine through limited review that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, and that the research to be conducted is within the scope of the obtained broad consent.

3. Expedited and Limited Review Requests:

For a complete listing of the required documents for an application for expedited or limited HRRC review, please review the Expedited or Limited Application Checklist (Form M).

The Co-Chair/Administrator will notify the Principal Investigator of the outcome (approval or request for revisions) of the expedited or limited review in writing within 20 business days following submission of a completed submission.

The determination is documented in Review Criteria Checklist (Form I). If instructed by the HRRC member(s) that reviewed the study, the Co-Chair/Administrator may review submitted revisions.

Reviewers may not disapprove a study via expedited procedures; disapproval may only occur by a majority vote at a convened HRRC meeting. If the reviewer recommends disapproval, the study must be referred to the full HRRC for review.

If there are multiple expedited reviewers and their determinations conflict, the Co-Chair/Administrator communicates with the members to determine whether concordance can be reached. If not, the Chair also reviews the research project and may either make the final decision or refer the matter to the full HRRC for review.

When an expedited review procedure is used, the HRRC Chair or Co-Chair/Administrator shall advise members during the next meeting of the Full Committee meeting of research projects that have been approved since the last convened meeting of the Full Committee.

C. Full HRRC Review

The HRRC Co-Chair/Administrator completes an initial review and may either:

- Request clarifications or additional documents, or
- Place the study on the next available meeting agenda.

The HRRC Co-Chair/Administrator assigns one or more HRRC members as primary reviewers, based on the nature of the research and the expertise of the HRRC member. Primary reviewers are encouraged to contact the Principal Investigator to ask questions or seek clarification about the research prior to the full committee meeting.

Each HRRC member receives the research project and all supporting documents prior to the meeting.

Investigators are invited to attend the meeting at which their research project will be reviewed. If present, a researcher will be asked to describe the research project, and the HRRC will ask any questions or request clarifications about the study.
After sufficient discussion, the HRRC members vote on each research protocol and the votes are recorded in the meeting minutes. See C. Voting and Actions on possible actions to be taken during a meeting. The determination is documented in Review Criteria Checklist (Form I).

All HRRC decisions regarding approval, disapproval or requests for revisions will be made by the HRRC within 30 business days and subsequently communicated to the Principal Investigator in writing within seven business days of the HRRC meeting where the submission is reviewed. If the HRRC decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the Principal Investigator an opportunity to respond in person or in writing.

For a complete listing of the required documents for an application for full HRRC review, please review the Full Review Application Checklist (Form P).

D. Cooperative Research (45 CFR § 46.1144)

Cooperative research projects are those research projects covered by this policy and procedures document which involve a covered entity and another institution or institutions. In the conduct of cooperative research projects, each covered entity and institution is responsible for safeguarding the rights and welfare of human subjects. With the approval of the appropriate director(s) of the covered entity or entities, a covered entity participating in a

cooperative research project may enter into a joint review arrangement, rely upon the review of another qualified IRB ('IRB of Record'), or make similar arrangements for avoiding duplication of effort.

For covered entities with research projects that are subject to the DARS HRRC, the DARS Commissioner is the only person who can approve a request for the HRRC to 'Defer' to an external IRB to serve as the 'IRB of Record' for the research project.

When the HRRC relies on an external IRB to serve as the 'IRB of Record,' the external IRB will be evaluated by the HRRC Chair or Co-Chair/Administrator to determine if it meets specific criteria for the protection of human research subjects and, if so, execute written agreements outlining specific responsibilities of each party.

There must be a formal written authorization agreement between the HRRC and the external IRB delineating the roles and responsibilities of each party. The agreement must include a commitment that the external IRB will adhere to the requirements of the external IRB's FWA. The HRRC has a standard form that may be used for this purpose, or the parties involved may develop their own agreement. This agreement must be kept on file with the HRRC and the external IRB, and made available to OHRP or any US federal department or agency conducting or supporting research covered by the FWA upon request.

To start this process, the Principal Investigator must submit the information identified in the Checklist and Instructions for Cooperative Research Projects (Form R).

The DARS Commissioner should make determinations to approve or disapprove cooperative research requests within 15 business days. If the DARS Commissioner approves a request for the DARS HRRC to 'Defer' to an external IRB to serve as the 'IRB of Record', the Co-Chair/Administrator will work with the external IRB to execute an "IRB Authorization Agreement" (Form S).

Once the research project has been reviewed and approved by the external IRB, the Principal Investigator must provide the DARS HRRC a copy of the external IRB approval.

V. HRRC Approval Timelines

When projects are federally funded, the Principal Investigator is responsible for sending a copy of the approval letter to the Grants and Contracts Office and/or the funding agency, as needed or appropriate.

The following approval timelines shall apply:

1. Exempt Review: Projects receive a three-year approval, beginning the date HRRC Co-Chair/Administrator issues the approval letter.

2. Expedited or Limited Review: Projects receive a one-year approval, beginning on the date HRRC Co-Chair/Administrator determines that any conditions for approval have been met and issues the approval letter.
3. Full Committee Review: The approval period begins the date of the convened meeting at which the HRRC voted to approve the study or approve with conditions. The default approval period is one year, but the HRRC may determine that a shorter review period is appropriate.

VI. Modifications to Research Projects

The Principal Investigator must conduct the research in accordance with the specific methods described in the application that was approved by the HRRC.

Whenever an ongoing project acquires a new Principal Investigator, or whenever there are changes (e.g., changes in consent procedures, addition of potentially sensitive items to research instruments, changes in treatment procedures) in the protocol or the subject population, a modification must be filed.

No changes in approved research may be initiated without HRRC review and approval, except when necessary to eliminate apparent immediate hazards to research subjects.

If a Principal Investigator wishes to make changes to a previously approved research project, these changes must first be submitted via the Modification Request (Form T) and approved by the HRRC.

The HRRC reviews modifications to previously approved research in accordance with the level of risk of the study as a whole and proposed changes. Modifications may be reviewed at a full HRRC meeting or via expedited procedures. Specifically:

1. Exempt reviews: Modifications are reviewed by HRRC Co-Chair/Administrator only, unless the changes are significant enough that the study no longer qualifies for exempt status. In this case, the amendment would receive either expedited or full HRRC review, in accordance with the level of risk of the changes.
2. Expedited reviews: Modifications receive expedited review, unless the changes raise the study to the level of more than minimal risk and full HRRC review is required. Expedited reviews may be conducted by the HRRC Co-Chair/Administrator only, or one or more additional reviewers may be assigned.
3. Full HRRC reviews: Minor modifications may receive expedited review by HRRC Co-Chair/Administrator and/or one or more reviewers. Significant modifications must receive full HRRC review. HRRC Co-Chair/Administrator, primary reviewer(s), and/or the Chair determine whether a change is “minor” vs. “significant”. If there is not consensus, the modification is sent to the full HRRC.

VII. Continuing Reviews, Status Updates and Project Closures

The HRRC shall conduct continuing review of research requiring ongoing review at intervals appropriate to the degree of risk, but not less than once per year for those requiring continuing review, and shall have authority to observe or have a third party observe the informed consent process and the research.

Depending on the degree of risk, the HRRC may conduct continuing review at a fully convened meeting, may conduct continuing review under expedited review procedures, or may not require continuing review.

Research that is classified as exempt will not require any further review after the initial approval. However, Principal Investigators should submit the Research Project Status Report (Form U) every three years. For research projects classified as exempt, principal investigators should send notification by email to the HRRC Co-Chair/Administrator within 30 calendar days after a research project closure. A Research Project Closure Report (Form X) is not required.

Research that is classified as expedited will not require any further review after the initial approval. However, Principal Investigators should provide an annual status update using the Research Project Status Report (Form U) and complete a Research Project Closure Report (Form X) within 30 calendar days after a research project closure.

For research projects classified as cooperative research using external IRB to serve as 'IRB of Record,' Principal Investigators should send notification by email to the HRRC Co-Chair/Administrator within 30 calendar days after a research project closure. A Research Project Closure Report (Form X) is not required.

Projects requiring continuing review should use the Continuing Review and Adverse Event Report (Form Y) and submit it to the HHRC Co-Chair/Administrator. Continuing Review reports, when required, are to be at least annually for all approved research projects, to ensure conformity with the approved proposal. The frequency of such reports shall be determined by the HRRC and shall be consistent with the nature and degree of risk of each research project. In addition, the Principal Investigator should complete a Research Project Closure Report (Form X) within 30 calendar days after a research project closure.

During the course of a research project, Principal Investigators should submit the Continuing Review and Adverse Event Report (Form Y) if unanticipated problem(s), safety issue(s), or other serious, unexpected adverse effect(s) or event(s) that are related or possibly related to your project arise.

During the course of a research project, Principal Investigators should submit the Research Inquiries, Comments or Concerns Report (Form V), when appropriate, to report to the HRRC any inquiries, comments and/or concerns from human research subjects, the community, and others.

If the Principal Investigator does not submit a Research Project Status Report (Form U) or Continuing Review and Adverse Event Report (Form Y) as required by the established deadline, the HRRC will close the research project.

For more information, please refer to sections 45 CFR § 46.104(d)(2)(iii), 46.104(d)(3)(i)(C), 46.104(d)(7), and 46.104(d)(8)(iii) of the revised Common Rule.

VIII. Research Project Non-Compliance

Principal Investigators must not start any aspect of research involving human subjects (e.g., recruitment, screening, etc.) until they have received written notification of HRRC approval.

The Principal Investigator is responsible for compliance with other laws and institutional rules (such as compliance with HIPAA, FERPA, biosafety regulations, etc.) and must provide documentation of any other reviews to the HRRC upon request.

Principal investigators shall report non-compliance with the approved research proposal to the HRRC.

If the HRRC determines that the research project fails to comply with the approved proposal or violates law or regulation, the HRRC or the DARS Commission may restrict or terminate further research, prohibit the Principal Investigator from presenting or publishing the research project results, and/or bar the Principal Investigator from conducting future studies that come before the HRRC.

Appendix A: List of All HRRC Forms (Required and Optional)

Form Name	Alphabetical Identifier
Conflict of Interest HRRC Member Statement: This form should be used by HRRC members and Ad-Hoc Reviewers prior to conducting any HRRC reviews or participating in an HRRC meeting.	A
HRRC Confidentiality Agreement: This form should be used by HRRC members and ad-Hoc reviewers prior to conducting any HRRC reviews or participating in an HRRC meeting and for any guests who are present during an HRRC meeting.	B
Guest Attendance Certification: Use this form to document each guest who attends at full HRRC meeting as well as their understanding of the guest responsibilities.	C
Conflict of Interest Disclosure Statement: The Principal Investigator should use this form to disclose or deny any financial interest(s) in the research project on behalf of the Principal Investigator, Co-Investigator(s), and Project Coordinator(s), as appropriate.	D
Listing of Co-Investigators: Use this form to identify any Co-Investigators on the research project.	E
HRRC Pre-Review Checklist: HRRC Chair or Co-Chair/Administrator should use this form to document a completed pre-review of an application.	F
Quality Improvement Determination Worksheet: This form helps researchers and the HRRC determine if a project is Quality Improvement (QI)/Quality Assurance (QA) or Human Subjects Research. This is not a required form.	G
Waiver of Informed Consent Request: Use this form to request waivers of the informed consent requirements.	H
Review Criteria Checklist: HRRC Chair or Co-Chair/Administrator should use this form to document a completed review of an application and that it satisfies the requirements of the HRRC.	I
Exempt Review Application Checklist: Use this form to ensure you have compiled and submitted all the required materials for an Exempt Review.	J
Request for Exempt Review: Use this form if you are requesting Exempt Review. The form identifies the exempt review qualifying category.	K
Exempt Review Application: Use this form to submit an Initial Application for Exempt Review view and clearance of human subject research.	L
Expedited or Limited Review Application Checklist: Use this form to ensure you have compiled and submitted all the required materials for an Expedited or Limited Review.	M

Request for Expedited or Limited Review: Use this form if you are requesting Expedited or Limited Review. The form identifies the expedited or limited review qualifying category.	N
Expedited or Limited Review Application: Use this form to submit an Initial Application for Expedited or Limited Review and clearance of human subjects' research.	O
Full Review Application Checklist: Use this form to ensure you have compiled and submitted all the required materials for a Full HRRC Review.	P
Full Review Application: Use this form to submit an Initial Application for Full HRRC Review and clearance of human subjects' research.	Q
Checklist and Instructions for Cooperative Research Projects: This form should be used by an applicant that would like to pursue cooperative research and use an external IRB as the IRB of Record for a research project. This form is a template; a principal investigator may submit a written and signed letter as long as it has the required elements.	R
IRB Authorization Agreement: This form should be used by the HRRC when it establishes an agreement with an external IRB to serve as 'IRB of Record' for a research project. This form is a template; another form or document may be used as long as it has the required elements.	S
Modification Request: Use this form to request a modification to a previously approved research project protocol.	T
Research Project Status Report: Use this form to provide an update on exempt or expedited or limited review projects that have been previously approved.	U
Research Inquiries, Comments or Concerns Report: Use this form to report inquiries, comments and/or concerns from human research subjects, the community, and others.	V
Research Project Closure Report: Use this form to notify the HRRC when your research project is completed.	X
Continuing Review and Adverse Event Report: Use this form to provide an information for the HRRC, or designated reviewer, for a continuing review of a project that have been previously approved and deemed subject to the HRRC's continuing review or to report unanticipated problem(s), safety issue(s), or other serious, unexpected adverse effect(s) or event(s) that are related or possibly related to your project.	Y