Welcome to the Institutional Review Board (IRB) web page for the South Carolina Department of Mental Health (SCDMH).

The department recognizes the need for safeguarding the rights and welfare of research subjects and their private health information. In accordance with Department of Health and Human Services regulations, the SCDMH has an established Institutional Review Board which is charged with these responsibilities. This web site is dedicated to providing the researcher with the tools and information necessary to protect these obligations and facilitate the approval process.

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Institutional Review Board Manual

About the IRB

Responsibilities of the IRB for Human Research Subject Protections

The South Carolina Department of Mental Health recognizes the need for safeguarding the rights and welfare of research subjects. In accordance with Department of Health and Human Services regulations, the South Carolina Department of Mental Health has an established Institutional Review Board (IRB) which is charged with these responsibilities.

The SCDMH IRB is responsible for and the approving authority to:

1. **Protect** the rights and welfare of **human subjects** involved in research. These are protections for the person (the subject) and protections for the information the subject provides. Responsibilities:

   - Ensure that subjects are adequately informed of the nature of the study;
   - Ensure that subjects’ participation is voluntary;
   - Ensure that the benefits of a study outweigh its risks;
   - Ensure that the risks and benefits of the study are evenly distributed among the possible subject population; and
   - Suspend human subject activity that violates regulations, policies, procedures, or an approved protocol, and report such violation and suspension to the Institutional Official.

2. **Protect** access to the subject’s **private health-related information and data**, e.g., diagnosis, treatment records, health status, billing records (HIPAA defined categories of information). Responsibilities:

   - Ensure that subjects are adequately informed on what private health-related data may be released to a researcher and that the release is voluntary
   - Ensure that all private health-related data that is released is adequately protected from further disclosure in any individually identifiable form
   - Ensure that there is an adequate plan to secure and protect the private health-related data during its use by the researcher
   - When it is not feasible to secure individual authorization for the release of private health-related information from a subject, ensure that all standards for de-identifying the data have been met or that requirements for a waiver of the authorization are met.
### About the IRB

**SCDMH Institutional Review Board Members**

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**Board Administrator**, Patricia A. Handley, DNP, MSN, RN  
Office: (803) 935-7886  email: IRB@scdmh.org

**Address:**  
Patricia A. Handley, DNP, MSN, RN  
Chief Nursing Officer  
South Carolina Department of Mental Health  
Division of Inpatient Services  
220 Faison Drive  
Columbia, SC 29203

**Schedule of Meetings:**  
**When:** Fourth Wednesday of each month, 11:00 AM  
**Where:** SCDMH Administration Building  
2414 Bull Street, Columbia SC 29202
SCDMH Documents Governing Human Subject Research

The South Carolina Department of Mental Health recognizes the need for research. It also recognizes that research conducted at SCDMH must have clear current and/or potential value to the patients and staff as well as the person, institution or agency requesting to conduct human subject research.

On July 1, 2008, the South Carolina Department of Mental Health (DMH) implemented a grant process under the Grants Administration Division to provide proper acquisition, administration, and monitoring of public and private funds for the agency.

The grant process requires the Grant Steering Committee to review all grant proposals to determine if the opportunity supports or advances the mission of the agency.

Pursuant to agency policy, only designated individuals (State Director or designee) are authorized to sign grant proposals, grant agreements, and award documents for the South Carolina Department of Mental Health. The State Director has also authorized the Grants Administrator to sign sub-recipient agreements and federal grant contracts for the agency. It is important to remember that only the above individuals can obligate the agency to state or federal grants/contracts. All principal investigators (PI’s), project directors, grant employees, and any staff who process grant related paperwork must adhere strictly to the grant policy, particularly for federal grant or contract awards.

What Constitutes Research?

**Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to common knowledge. Some demonstration and service programs may include research activities which must be reviewed by the Institutional Review Board.

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

1. Data through intervention or interaction with the individual.
   - **Intervention** includes both physical procedures by which data are gathered (e.g., 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.

2. Identifiable **private information**.
   Individuals can reasonably expect that observations, notes, and/or recordings about their behavior will be kept private. If the individual can be identified by the researcher or anyone else (directly or indirectly through a coding system linking the research subject to the information), the information is deemed private.
SCDMH Documents Governing Human Subject Research  
Principles of Ethical Research  

The following principles are to be followed by the SCDMH Institutional Review Board (IRB) and all personnel in formulating and implementing research projects that involve human subjects.  

GENERAL PRINCIPLES  

A. Projects directly involving and/or individually identifying human subjects shall conform to the scientific, legal, and ethical principles which guide all research and shall emerge from a sound theoretical basis and follow accepted research design.  

B. Ethical aspects of the study must be clearly stated in the project design.  

C. Projects should be conducted only by professionally and scientifically qualified individuals. When appropriate, medical liaison or supervision should be provided. The Institutional Review Board shall determine, prior to approving the project, that the Principal Investigator is an individual of sufficient competency and maturity or judgment and is on the staff or sponsored by the facility involved in the project.  

D. Projects involving human subjects at risk shall not be implemented unless the anticipated risks to the subject are so outweighed by the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks. The evaluation of such risks should include not only possible physical injury, but also psychological or social injury and alterations of personality.  

"Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in research.  

If evidence of greater risks than that originally anticipated develops, the Principal Investigator will immediately discontinue the project and promptly report it to the IRB.  

E. The Principal Investigator shall take all responsible steps and precautions to provide for the safety and welfare of subjects who consent to participate in projects.  

F. The Principal Investigator shall take all reasonable steps to respect the privacy rights of any human subject.  

G. Experimentation shall be planned so as to avoid unnecessary pain, embarrassment, suffering, or inconvenience to the subject, or their family or guardian.  

INFORMED CONSENT  

A. No project directly involving and/or individually identifying a human subject shall be undertaken without the subject's or the individual's legally authorized representative's freely given written informed consent.  

"Informed consent" means the knowing consent of an individual or the individual's legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.
B. The purpose of an Informed Consent is to fully disclose the purpose and risks of participation in the research and let the potential subject decide to participate or not on the basis of that disclosure. This form will have the full information described in this section, as well as the date the consent form was signed and the name and contact information of the individual who supplied the subject with the information.

C. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights or to release or appear to release the investigator, sponsor, the institution, or its agents from liability for negligence.

D. Subjects who are legally or functionally incompetent shall participate only when the consent has been given by the subject's legally authorized representative. The research subject must be given a copy of the Informed Consent.

E. Denial of consent to participate in a project shall not be a cause for denying or altering the indicated services to that patient.

F. When children are being solicited as research subjects, the researcher shall consider adequate provisions for obtaining the child's Informed Consent. The researcher shall, in determining whether children are capable of consenting or assenting, take into account the ages, maturity and the psychological state of the children involved. The researcher shall be specific in identifying the ages of children for whom Informed Consent will be solicited, the ages for which parental (or guardian) permission is to be obtained and whether one or both parents must consent. The latter shall be based upon the degree of risk involved in the research study (See section in Table of Contents: Special Population Requirements - Children).

G. The subject shall be allowed to withdraw consent and discontinue participation in a project at any time without affecting their status in the program.

H. The basic elements of information necessary to such consent include:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subjects' participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

2. A description of any reasonably foreseeable risks or discomforts to the subject.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
6. An explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related injury to the subject.

7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

8. 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.

I. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject.

J. The requirement for obtaining an informed consent may be waived if either:

1. The only record linking the subject and the research would be the consent document and the principal risk to the subject would be potential harm resulting from a breach of confidentiality; or

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
Research that Requires Approval

Case Studies

Although case studies usually do not meet the Common Rule definition of research (a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge) and as such do not require IRB review and approval all case studies must be reviewed by the applicable supervisor(s).

Case Studies and Protected Health Information

- Case studies that do not involve the receipt, disclosure or use of Protected Health Information, “PHI” (i.e., health information paired with identifiers such as name, SS#, DOB, address, etc.) do not require a signed “AUTHORIZATION TO DISCLOSE SCDMH PROTECTED HEALTH INFORMATION” or other privacy authorization to receive, disclose or use the non-PHI.

- All case studies that involve the receipt, disclosure or use of PHI must be reviewed by the local Privacy Officer (and if the use involves computer PHI, it must also be reviewed by the local Security Officer) for applicable Privacy Practices and other requirements (see Privacy Practices Directive 837-03 and applicable Security Policies.)

Case Studies Requiring IRB Approval

Regardless of the number of study subjects, the activity is considered research and requires IRB approval if any of the following is present,

- Investigational drug(s) or device(s) are involved (off-label use of an approved drug or device for the sake of an individual patient does not constitute research).

- There is a clear intent before treating the patient to use systematically collected data that would not ordinarily be collected in the course of clinical practice in reporting and publishing the case study.

- There is a plan to perform the treatment on some individuals but not on others.

- There is intent to manipulate medications (even approved ones) to determine maximum effectiveness, or to test if they work consistently well.

- Extra tests are conducted for the sake of reportability.

- There is a protocol/study plan.

- Records or data sheets are maintained separate from clinical records (particularly with identifiers).

- The primary purpose is to answer a research question, not to provide care.

- There is a possibility that the treatment might yield a case series if it is effective in others (e.g., testing a hypothesis).

- There is intent to publish a report that is analytical not descriptive.
Research that Requires Approval

Exempt Projects

Research projects with human subjects may be exempt from Institutional Review Board (IRB) review only if they pose **minimal risk** to subjects. **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.

The following three categories of human subject research are exempt from IRB review:

1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   - Information obtained is recorded in such a manner that human subjects cannot be identified, **directly or through identifiers linked to the subjects**; and
   - 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, or reputation.
   **Note:** The exemption for research involving survey or interview procedures or observation of public behavior does not apply to research with children.

2. Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens, if:
   - These sources are publicly available; or
   - The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
   **Note:** The exemptions listed in items 1 and 2 above do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization.

3. Program Evaluation: The SCDMH IRB will exempt from IRB review data collection activities that are:
   - **Minimal risk:** and
   - For the sole purpose of evaluating the effectiveness of a service delivery program.
   Program evaluation differs from research in a number of ways. For example, program evaluation is not intended to add to a body of common knowledge; it may be an evaluation component of a service grant whose effectiveness is already documented; it has no control group; and/or it may be a quality improvement activity reviewing data collected as a routine part of the treatment or assessment. If there is doubt about whether data collection is program evaluation or research, it should be submitted to the IRB.

**Note:** Categories 1 and 2 are a condensation of §46.101, b, 1-6 of the Code of Federal Regulations, Title 45, Part 46. The full text of federal regulations for exempt projects may be found at: [mailto:https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML]
Research That Requires Approval

Expedited Review Procedures

Certain minimal risk projects, not eligible for exempt status, may be approved without full Institutional Review Board (IRB) review. Research activities may be reviewed through the expedited review procedure that:

A. Present no more than minimal risk to human subjects; and

B. Involve only procedures listed in one or more of the following categories.

- Clinical studies of certain drugs and medical devices;
- Collection of small amounts of blood samples
- Prospective collection of certain biological specimens, e.g., hair/nail clippings, sputum, mucosal and skin cells, by noninvasive means;
- Collection of data through noninvasive procedures routinely employed in clinical practice, e.g., weighing or testing sensual acuity, EEG, EKG, ultrasound, or moderate exercise;
- Research involving existing materials (data, documents, records, or specimens) collected solely for non-research purposes (such as medical treatment, diagnosis, or treatment planning);
- Collection of data from voice, video, digital, or image recordings.
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Continuing review of certain research previously approved by the IRB.

These categories apply regardless of the age of subjects. For a review of the complete text, go to mailto:https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

The activities (above) should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The expedited review procedure may not be used if:

1. Identification of the subjects and/or their responses 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; or

2. The research deals with sensitive aspects of the subject’s behavior (e.g., illegal conduct, drug/alcohol abuse, sexual abuse, sexual preference, domestic violence) or studies involving deception.
Research that Requires Approval

Full Board Review Projects

All research projects not meeting the criteria for Exempt or Expedited Review will be reviewed for approval by the full Institutional Review Board (IRB). Prospective researchers are always welcome to attend. When the IRB is able to discuss concerns and get clarifications from the researcher, delays in approval are frequently avoided. Please contact the IRB Administrator via email: IRB@scdmh.org or call 803-935-7886 to arrange attendance.

Research that Requires Approval

Continuing Review Requirement

All research approved by the SCDMH Institutional Review Board is subject to Continuing Review, and no project may continue beyond one (1) year without re-approval. The time limit for submission of the Continuing Review Form is established during the initial review of the project.
Approval Process

Required Protocol Information

The Institutional Review Board (IRB) requires specific information to ensure the protection of research subjects and has developed a Project Application Form to capture this information. Researchers are requested to complete and submit this Project Application Form along with a full copy of any research protocol that exists.

The minimal requested information includes:

1. A description of, and scientific rationale for, the proposed research activity; and

2. A discussion of the human subject protection issues which address, at a minimum:
   - Risks to subjects;
   - All experimental procedures;
   - Anticipated benefits to subjects, if any;
   - Anticipated number of subjects;
   - Subject selection, recruitment procedures, and subject inclusion/exclusion criteria:
   - Informed consent document and process to be used; and
   - Appropriate additional safeguards if potentially vulnerable subjects are to be enrolled, i.e., the elderly, prisoners, children, cognitively impaired people, or people who are economically or educationally disadvantaged.

The information should be in sufficient detail to allow the IRB to address the following areas:

- Proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.
- 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.
- Risks to subjects are minimized.
- Subject selection is equitable.
- Informed consent is obtained from research subjects or their legally authorized representative(s).
- Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.
- Subject privacy & confidentiality are maximized.
Approval Process

Required Informed Consent Information

Perhaps most central in Institutional Review Board (IRB) deliberations is the informed consent, for it is this document which explains to a potential research subject exactly what is being asked of him/her and the inherent risks/benefits of participation in the research.

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

The IRB may waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

An investigator shall seek an informed consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and under circumstances that minimize the possibility of coercion or undue influence.

The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Investigators are encouraged to write informed consents at the 8th grade reading level.

No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, sponsor, the institution, or its agents from liability for negligence.

The eight elements that are required for all informed consent forms include:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subjects' participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
6. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of research-related injury.
7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

8. For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

In addition, there are five additional elements that should be considered for inclusion depending on the nature of the research project. They include:

1. A statement that the treatment/procedure may involve risks to the subject (or to embryo/fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject.
Approval Process
Steps, Timelines & Deadlines to Getting a Research Project Approved

Proposals must be approved by all bodies governing the researcher that are external to DMH (i.e., university IRB, dissertation committee, etc.) prior their submission to the DMH Institutional Review Board (IRB).

The following steps, which are also presented graphically below, outline the procedure for approving research proposals in the South Carolina Department of Mental Health.

1. Submit the proposal to the appropriate DMH facility for site approval (Community Mental Health Center Director or In-patient Facility Director). The Center or Facility Director should then submit the Estimated Research Costs Form and a letter of support to their respective Division Director using the Facility/Center Director Letter of Support. The Division Director indicates on the same form his/her approval/disapproval of the project. If the Division Director approves, proceed to step #2 below. IRB approval does not ensure that any particular DMH facility will allow a research project to be conducted at their site.

Submit via email the SCDMH “Project Application for Research Involving Human Subjects,” Facility/Center Director Letter of Support and the Estimated Research Costs Form to the IRB Administrator email box IRB@scdmh.org or mail to, IRB Administrator South Carolina Department of Mental Health, 220 Faison Drive, Columbia, SC 29203. These two documents must be submitted by the first Wednesday of the month to be eligible to be reviewed during that month’s IRB meeting. Non-SCDMH employees must sign and submit the Unaffiliated Investigator Agreement and Privacy Practices Agreement.

2. If the research proposal is approved by the Deputy Director it will be reviewed by the IRB Chair to determine its status (as either Exempt, Expedited, Full Board Review).

3. If the project meets the criteria for Exemption from IRB review, you will receive written notification within about four days from the IRB Administrator or IRB Chair.

4. If the proposal is eligible for Expedited Review, it will be reviewed within about four days and the researcher notified. If it is not eligible for Expedited Review, or if concerns are raised by the reviewers, full IRB review is required.

5. The SCDMH IRB meets at 11:00 am on the fourth Wednesday of each month. The researcher is encouraged to attend this meeting. Proposals to be reviewed by the SCDMH IRB must be submitted to IRB Administrator by the first Wednesday of each month in order to be reviewed by IRB that same month. Submissions received after the first Wednesday of a given month potentially will be reviewed by the IRB the following month.

6. Following review, the DMH IRB will exercise one of three options: full approval of proposal; disapproval of proposal; or approval pending receipt of modifications to the proposal. If modifications are required, they are explicitly communicated to the researcher who, upon fulfilling the requirements, does not usually have to resubmit the proposal for full IRB review. Upon receipt of the modified proposal, IRB approval is given.
Researchers should be aware that any modifications to research proposals which may be required by DMH could necessitate re-approval by the researcher's governing body and/or any other IRB that has authority over the research.

*Note: Any grant funded research project must be coordinated through the DMH Grants Coordinator, as specified in the DMH Grant’s Directive.*
Approval Process

Required Training for Investigators

All investigators and key personnel submitting NIH applications are required by NIH to complete training in human subject protection and submit proof of training completion prior to the award of funds. “Key personnel” include all individuals responsible for the design and conduct of the study.

This training is available on-line from a variety of sites, including:

- [https://www.citiprogram.org/](https://www.citiprogram.org/) (Organizational membership required)
  or through any other acceptable source. Contact the SCDMH IRB Administrator if assistance is required.

Certificates of completion should be submitted to the IRB Administrator. Upon receipt, the IRB Administrator will furnish the researcher with the required acknowledgment letter.

Contact the SCDMH IRB Administrator or Chair if assistance is required.

Send Training Completion Certificates via email to: IRB@scdmh.org
  IRB Administrator or Chair South Carolina Department of Mental Health
  220 Faison Drive
  Columbia, SC 29203

Non-SCDMH Employees Requesting Research Permission

All non-SCDMH employees requesting permission for subject contact and/or access to individually identifiable Protected Health Information (PHI) are required to read the [Unaffiliated Investigator Agreement and the Privacy Practices Agreement](http://phrp.nihtraining.com/users/login.php) and submit the [Agreement Signature Page](http://phrp.nihtraining.com/users/login.php) to the IRB Administrator as part of their Project Application.
HIPAA and Research

What is the Privacy Rule?

The HIPAA Privacy Rule is a set of regulations that are separate and distinct from the Protection of Research Subjects regulations. It pertains to the private health information of individuals, not the subject’s participation in the research project. The “Privacy Rule” – a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 – protects certain health information of individuals, living and deceased.

Note: The Health Insurance Portability and Accountability Act (HIPAA) sections are reproduced from http://privacyruleandresearch.nih.gov/pr_08.asp.

How HIPAA Affects a Researcher

The Privacy Rule of HIPAA (Health Insurance Portability and Accountability Act) regulates the way DMH (a covered entity) may use or disclose individually identifiable health information known as protected health information (PHI). In general, the Privacy Rule requires an individual to provide his/her signed permission, known as an Authorization before a covered entity can use or disclose the individual's PHI for research purposes.

HIPAA Authorizations may be included as content in an Informed Consent or they may be a separate document. In either case, the “Core Elements” that must be included in an Authorization may be found at Obtaining Authorizations from Subjects.

Under certain circumstances the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual’s Authorization. The documentation required for a waiver of the Authorization may be found at Criteria for Requesting Waivers.

For additional information on HIPAA and special requirements for researchers, see: http://privacyruleandresearch.nih.gov/pr_02.asp

Conditions for Use/Disclosure of PHI

Protected Health Information (PHI) may be used and disclosed in research under three conditions:

1. the individual signs a written “authorization” giving permission;
2. the information or data is de-identified; or
3. PHI may be used and disclosed for research without an Authorization in limited circumstances. This may be accomplished through:
   o Waiver
   o Data collection preparatory to research (See web site below for description).

For other conditions under this heading, see http://privacyruleandresearch.nih.gov/pr_08.asp#8c
HIPAA and Research

Obtaining Authorization from Subjects

The first condition under which Protected Health Information (PHI) may be used and disclosed in research is by obtaining the subject's written permission.

The Written Authorization: A valid Privacy Rule Authorization is an individual's signed permission that allows a covered entity (SCDMH) to use or disclose the individual's PHI for the purposes stated in the Authorization and to the recipient or recipients as stated in the Authorization.

The Privacy Rule requires that an Authorization pertain only to a specific research study, not to nonspecific research or to future, unspecified projects. The Privacy Rule considers the creation and maintenance of a research repository or database as a specific research activity, but the subsequent use or disclosure by a covered entity of information from the database for a specific research study will require separate Authorization unless a waiver is granted. If an Authorization for research is obtained, the actual uses and disclosures made must be consistent with what is stated in the Authorization. In SCDMH, Authorizations are usually managed in the individual patient’s Community Mental Health Center or inpatient facility.

An Authorization can be combined with an informed consent document. Whether combined with an informed consent or separate, an Authorization must contain the specific core elements and required statements stipulated in the Rule. These elements may be reviewed at: http://privacyruleandresearch.nih.gov/authorization.asp

Authorization Core Elements

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure. An Authorization for research uses and disclosures need not have a fixed expiration date or state a specific expiration event. "End of the research study" or "none" is permissible for research, including for the creation and maintenance of a research database or repository.
- Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.

Authorization Required Statements

- A statement of the individual's right to revoke his/her Authorization and how to do so, and, if applicable, the exceptions to the right to revoke his/her Authorization or reference to the corresponding section of the covered entity's notice of privacy practices.
- Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on Authorization, including research-related treatment and consequences of refusing to sign the Authorization, if applicable.
o A statement of the potential risk that PHI will be re-disclosed by the recipient. This may be a
general statement that the Privacy Rule may no longer protect health information disclosed to the
recipient.

De-Identified Data

The second condition under which Protected Health Information (PHI) may be used and disclosed in
research is by de-identifying the data. Variations on this de-identification process may be
reviewed at http://privacyruleandresearch.nih.gov/pr_08.asp.

Under this condition, SCDMH's Institutional Review Board (IRB) may approve the use/disclosure of
data/information without an individual’s authorization if it determines that health information is
not individually identifiable. To meet this condition, all of the following identifiers must be
removed before the data is released to the researcher.

1. Names.

2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP
   Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if,
   according to the current publicly available data from the Bureau of the Census:
   A. The geographic unit formed by combining all ZIP Codes with the same three initial
digits contains more than 20,000 people, or
   B. The initial three digits of a ZIP Code for all such geographic units containing 20,000
      or fewer people are changed to 000.

3. All elements of dates (except year) directly related to an individual, including birth date, admission
date, discharge date, date of death; and all ages over 89 and all elements of dates (including year)
indicative of such age, except that such ages and elements may be aggregated into a single
category of age 90 or older.

4. Telephone numbers.

5. Facsimile numbers (Fax).

6. Electronic mail addresses (E-mail).

7. Social security numbers.

8. Medical record numbers.

9. Health plan beneficiary numbers.

10. Account numbers.


12. Vehicle identifiers and serial numbers, including license plate numbers.


15. Internet protocol (IP) address numbers.

16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.

18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

Criteria for and Requesting Waivers

Without the Written Authorization Disclosure/Use

The third condition under which a covered entity may approve the use/disclosure of data/information is by waiver of the Authorization requirement.

Criteria for Waiver

Documentation of the waiver must include a statement that the Institutional Review Board (IRB) has determined that the waiver, in whole or in part, satisfies the following criteria:

- The use or disclosure of the Protected Health Information (PHI) involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
  - An adequate plan to protect health information identifiers from improper use and disclosure.
  - An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so).
  - Adequate written assurances that the PHI will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research as permitted by the HIPAA regulations.

- The research could not practicably be conducted without the waiver or alteration.

- The research could not practicably be conducted without access to, and use of, the PHI.

To Request a waiver of authorization from the IRB the researcher MUST:

1. Provide a brief description of the PHI to be used.

2. Use the following methods to ensure minimal risk to privacy of individuals:

   A. Describe an adequate plan to protect the identifiers from improper use or disclosure.

   B. Describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or retentions is required by law.

   C. Assure the IRB in writing that the PHI will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research as permitted by the HIPAA regulations.
Researchers may submit the above information by completing the Request for a Waiver or an Alteration of Individual Alteration.

Activities Preparatory to Research

A covered entity may approve the use/disclosure of data/information without an Authorization or waiver as “preparatory to research,” such as to aid study recruitment. However, the provision does not permit the researcher to remove protected health information from the covered entity’s site. As such, a researcher who is an employee of SCDMH could use protected health information to contact prospective research subjects. The preparatory research provision would allow such a researcher to identify prospective research subjects for purposes of seeking their Authorization to use or disclose protected health information for a research study.

For recruitment purposes, the researcher cannot contact potential research subjects if they do not have a direct treatment relationship with those subjects. If the researcher does not have a direct treatment relationship with the subjects, they must approach the subjects through someone who does have a direct treatment relationship with the subjects. The outside researcher could obtain contact information through a partial waiver of individual authorization by an IRB.
Special Population Requirements

Children: Special Provisions and Requirements

Definition: defined by South Carolina law as “persons under the age of 16.” Adolescents, age 16 or older, may give informed consent independent of parental informed consent or that of legal guardians, as may emancipated minors.

Exempt:
Research involving the use of educational tests (cognitive, diagnostic, aptitude, and achievement) with children as subjects is exempt from Institutional Review Board (IRB) review provided that:

1. Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; and

2. Any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note: Research with children involving survey or interview procedures or observation of public behavior may not be exempted from IRB review.

Expedited Review:
All categories of research eligible for Expedited Review approval are applicable to research involving children although there are special limitations on blood samples as specified in http://www.hhs.gov/ohrp/policy/populations/index.html

Risk Determination in Research Involving Children:
In weighing the risk/benefit equation for research proposals involving children, there are four categories into which allowable research may fall and which govern the IRB decision-making process. These are:

1. Research presenting no greater than minimal risk to children. Research in this category must include adequate provisions for soliciting the assent of the children and the permission of parents or guardians. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted.

2. Research involving greater than minimal risk but presenting the prospect of direct benefit to individual child subjects. Within this category the IRB must determine that:
   o The research risk is justified by the anticipated benefit to the subjects;
   o The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
   o Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted.

3. Research involving greater than minimal risk to children and an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring
procedure which is not likely to contribute to the well-being of the subject. Research in this category may be approved only if the IRB finds that:

- The risk represents a minor increase over minimal risk;
- The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- The intervention or procedure is likely to yield common knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians. Where permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. For a discussion on Assent/Consent considerations, refer to [http://answers.hhs.gov/ohrp/questions/7267](http://answers.hhs.gov/ohrp/questions/7267)

4. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

An IRB must find that the research in this category presents a reasonable opportunity to further understanding, prevention or alleviation of a serious problem affecting the health or welfare of children. Where permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

**Special Population Requirements**

**Prisoners: Special Provisions and Requirements**

In as much as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research, additional safeguards are imposed for their protection.

"Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**Exempt:** There are no categories of research involving prisoners as subjects that are exempt.

**Expedited Review:**

All categories of research eligible for Expedited Review approval are applicable.
Permitted Research Involving Prisoners:

Biomedical or behavioral research may involve prisoners as subjects only if the proposed research involves solely the following:

- Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

- Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to subjects;

- Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or

- Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

Research that fall into one of the above categories may be approved only if the Institutional Review Board (IRB) finds that all of the following are applicable:

1. Any possible advantages accruing to the prisoner through his or her participation in the research (when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison) are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

3. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

4. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

5. Where the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects of this fact.
GUIDELINES FOR AN INFORMED CONSENT FORM TO BE USED IN RESEARCH PROJECTS INVOLVING HUMAN SUBJECTS

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, sponsor, the institution, or its agents from liability for negligence.

ELEMENTS OF AN INFORMED CONSENT

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subjects' participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- 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.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

Any additional costs to the subject that may result from participation in the research.

The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

**Research and Procedures**

The information provided to subjects should:

- Make clear that the activity involves research and describes the overall experience that will be encountered;
- Explain the procedures, including any parts that are experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues);
- Include the expected length of time it will take for study visits or scheduled procedures, as well as, the total expected length of participation.

**Risks**

- All reasonably foreseeable risks, discomforts, inconvenience, and harms that are associated with the research activity, should be described.
- Investigators should be forthcoming about risks and not understate or gloss over reasonably foreseeable risks.
- If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are recontacted or newly contacted.

**Benefits**

- Any benefits to subjects or others which may reasonably be expected from the research should be described.
- Investigators should be frank about benefits and not overestimate or magnify the possibility of benefit to the subject. If there is no reasonable expectation of benefit, the subject should be told this.
- Payment to subject should not be listed or described in the Benefits section.

**Alternatives to Participation**

- Appropriate alternatives to participating in the research project, particularly alternatives that might be advantageous to the subject, should be described. For example, in drug studies, the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
- Investigators should be reasonably specific about describing the nature and type of available alternatives. It is not sufficient simply to state that “the researcher will discuss alternative treatments” with the subject.
Confidentiality Protections

The regulations require that subjects be told the extent to which confidentiality of research records identifying the subject will be held in confidence. For example, sponsors, funding agencies, regulatory agencies, and the IRB may review research records. Some studies may need sophisticated encryption techniques to prevent confidentiality breaches or a Certificate of Confidentiality to protect the investigator from being compelled to release (e.g., under subpoena) subjects' names or identifiable private information.

Compensation for Injury

If research-related injury (i.e., physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given as to whether any compensation and treatment will be provided and if so, what these consist of and where further information may be obtained. **Note that the regulations do not limit injury to "physical injury." This is a common misinterpretation.**

The regulations prohibit

(i) Requiring subjects to waive any of their legal rights, and (ii) leading subjects to believe they are waiving their rights. Consent language regarding compensation for injury must be selected carefully so that subjects are not given the impression that they have no recourse to seek satisfaction beyond the institution's voluntarily chosen limits.

Contact Persons

The regulations require the identification of contact persons to answer subjects' questions about the research and their rights as research subjects. Subjects must also be informed as to whom to contact in the event of any research-related injuries.

These areas must be explicitly stated and addressed in the consent process and documentation.

Contact Persons

A single contact person is not likely to be appropriate to answer questions in all areas. This is because of real or apparent conflicts of interest. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects may best be referred to persons not on the research team. These questions could be addressed to the IRB, an ombudsperson, an ethics committee, or other informed individual or committee.

Each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

Voluntary Participation

The regulations require statements regarding voluntary participation and the right to withdraw at any time. Subjects must be informed that:

- Participation is voluntary;
- Subjects may discontinue participation at any time;
- There is no penalty or loss of benefits for refusing to participate or discontinuing participation.
Additional Protections for Vulnerable Populations

- The regulations identify three populations as needing additional protections. These are Subpart B Additional DHHS Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research; Subpart C Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects; and Subpart D Additional DHHS Protections for Children Involved in Research. The provisions of these subparts must be met for research to be approved.
- Incompetent adults cannot give consent – this may include the developmentally disabled, the cognitively-impaired elderly, and unconscious or inebriated individuals. Only legally authorized representatives in accordance with state law can give permission for incompetent adults to participate in research.
- In addition to the population described above, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as economically or educationally disadvantaged persons or subordinates, additional safeguards shall be included to protect the rights and welfare of the subjects.

Waiver of Consent

Under certain circumstances specified in the HHS regulations, the IRB may approve a consent procedure that does not include some or all of the elements of informed consent, or may waive the requirements for obtaining informed consent. To do so, the IRB must find and document that:

- The research involves no more than minimal risk to subjects;
- The waiver will not adversely affect the rights and welfare of subjects;
- The research could not practicably be carried out without the waiver; and
- Whenever appropriate, the subjects will be debriefed – provided with additional pertinent information – after they have participated in the study.

➤ NOTE – FDA regulations do not provide for a waiver of consent, except in emergency situations.
The Consent Process

Documentation of Consent

The information that is given to the prospective subject, or his/her representative, must be in language understandable to the subject or representative.

Consent forms should be written at a level appropriate to the understanding of the subjects to be enrolled; technical language should be avoided.

OHRP strongly discourages use of the "first person" in consent documents (e.g., "I have been fully informed about ...”). Such statements unfairly ask subjects to make statements that the subject is not in a position to verify (e.g., the subject has no way to verify that the investigator has provided full and complete information).

Except as allowed below, the informed consent must be documented by the use of a written consent form approved by the IRB and signed by the subject or legally authorized representative. A copy shall be given to the person signing the form.

Waiver of Documentation of Consent

The IRB may waive the requirement for written documentation of consent in cases where:

- The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research; and the consent document is the only record linking the subject with the research; each subject will be asked if they want documentation to remain with them or with the research and the subject's wishes will govern;

OR

- The research presents no more than minimal risk and involves procedures that do not require written consent when performed outside of a research setting.

Resource Material

University/College Degree Student Sponsorship Criteria

The SC Department of Mental Health recognizes and supports the need for student led/conducted research as a vital component of degree programs at universities and colleges. The Department also acknowledges that many students may be unable to financially compensate SCDMH Divisions, Centers, and/or Facilities for the assistance required by the student to complete required degree completion research. SCDMH offers ten research sponsorships to students conducting research to fulfill degree requirements. Student must meet the following criteria in order to apply for sponsorships.

1. The student (including student employees) must be enrolled in an accredited College or University program.

2. The research must have clear current and/or potential value to the patients and staff as well as to the student requesting to conduct human subject research.

3. The student must submit a letter to the Director of the Center, facility or Division detailing the estimated time and resources the department may be expected to provide to assist the student in fulfilling their required degree related research project. That letter must be included in the sponsorship application packet.
4. The research must be in-line with the agency mission “To Support the Recovery of Persons with Mental Illnesses.

5. The research topic must have approval of the students’ thesis and/or dissertation committee.

6. Research must be conducted in accordance with all Federal Regulations that exist to protect the rights and welfare of human subjects involved in research including seeking Institutional review Board when appropriate.

7. Students must complete the IRB/Research approval and application process, complying with SCDMH Institutional Review Board decisions.

8. Students, regardless of financial, need may not conduct any research without the approval of the Facility/Center or division Director, the Deputy Director and, if necessary, the SCDMH Institutional review Board.

9. Sponsorship packet must include:
   - Project Application for Research
   - Facility/Center Director Letter of Support
   - Estimated Cost Associated with Outside Research form
   - Unaffiliated Investigator Agreement (Non-SCDMH Employee) If applicable
   - Privacy Practices Agreement (HIPAA)
   - Non-Employee Signature Page If applicable
   - Request for a Waiver or an Alteration of Individual Authorization If applicable

(Note: As SCDMH is responsible for the safety and security of its clients, patients and employees therefore only the SCDMH has the authority to grant an investigator(s) permission to conduct research on, with or for clients, patients, or staff. Although a student may seek research approval from their university or college IRB, no student can substitute that for the approval of the SCDMH IRB.)
Common Rule

Summary of the Major Changes in the Final Rule

The final rule differs in important ways from the NPRM. Most significantly, several proposals are not being adopted:

- The final rule does not adopt the proposal to require that research involving nonidentified biospecimens be subject to the Common Rule, and that consent would need to be obtained in order to conduct such research.
- To the extent some of the NPRM proposals relied on standards that had not yet been proposed, the final rule either does not adopt those proposals or includes revisions to eliminate such reliance.
- The final rule does not expand the policy to cover clinical trials that are not federally funded.
- The final rule does not adopt the proposed new concept of “excluded” activities. Generally, activities proposed to be excluded are now either described as not satisfying the definition of what constitutes research under the regulations or are classified as exempt.
- The proposed revisions to the exemption categories have been modified to better align with the long-standing ordering in the final rule. The final rule does not include the proposed requirement that exemption determinations need to be made in specified ways.
- The final rule does not include the proposed standardized privacy safeguards for identifiable private information and identifiable biospecimens. Aspects of proposals that relied on those safeguards have been modified or are not being adopted.
- The final rule does not adopt the most restrictive proposed criteria for obtaining a waiver of the consent requirements relating to research with identifiable biospecimens.

The final rule makes the following significant changes to the Common Rule:

- Establishes new requirements regarding the information that must be given to prospective research subjects as part of the informed consent process.
- Allows the use of broad consent (i.e., seeking prospective consent to unspecified future research) from a subject for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens. Broad consent will be an optional alternative that an investigator may choose instead of, for example, conducting the research on nonidentified information and nonidentified biospecimens, having an institutional review board (IRB) waive the requirement for informed consent, or obtaining consent for a specific study.
- Establishes new exempt categories of research based on their risk profile. Under some of the new categories, exempt research would be required to undergo limited IRB review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens.
- Creates a requirement for U.S.-based institutions engaged in cooperative research to use a single IRB for that portion of the research that takes place within the United States, with certain exceptions. This requirement becomes effective 3 years after publication of the final rule.
- Removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care.

Other minor changes have been to improve the rule and for purposes of clarity and accuracy.
Human Subject Regulations Decision Charts

February 16, 2016

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. OHRP welcomes comment on these decision charts. The charts address decisions on the following:

- whether an activity is research that must be reviewed by an IRB
- whether the review may be performed by expedited procedures, and
- whether informed consent or its documentation may be waived.

Considerations

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?

Chart 2: Is the Human Subjects Research Eligible for Exemption?

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

Chart 8: May the IRB Review Be Done by Expedited Procedures?

Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?

Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]

**NO**

Will the only** involvement of human subjects be in one or more of the following categories?

Research conducted in established or commonly accepted educational settings, involving normal education practices?

If not exempt under (b)(1)

Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

If not exempt under (b)(2) or (b)(3)

Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?

If not exempt under (b)(4)

Research studying, evaluating, or examining public benefit or service programs?

If not exempt under (b)(5)

Research involving taste and food quality evaluation or consumer acceptance studies?

If not exempt under (b)(6)

No exemptions to 45 CFR part 46 apply.

Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.

**“Only”** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

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February 16, 2016
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

From Chart 2

Is the research only** conducted in established or commonly accepted educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

** “Only” means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

YES

Does the research study involve only normal education practices? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)

NO

Research is not eligible for 45 CFR 46.101(b)(1) exemption.

Next

NO

Return to Chart 2 and consider whether 45 CFR 46.101(b)(2) exemption applies.

YES

Research is eligible for 45 CFR 46.101(b)(1) exemption from 45 CFR part 46 requirements.

February 16, 20126
Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

From Chart 2

Does the research involve only** the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

- **"Only"** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

- Research is not eligible for exemption under 45 CFR 46.101(b)(2) or (b)(3).

- Return to Chart 2 and consider whether 45 CFR 46.101(b)(4) exemption applies.

- Only research involving only** educational tests or observation of public behavior without participation by the investigator in the activities being observed is exempt under 45 CFR 46.101(b)(2).

Does the research involve children to whom 45 CFR part 46, subpart D applies?

- YES

- Research is not eligible for exemption under 45 CFR 46.101(b)(2).

- However, the 45 CFR 46.101(b)(3) exemption might apply.

- Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

- NO

- NO

- Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.

- YES

- Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?

- NO

- YES

- Research is eligible for exemption under 45 CFR 46.101(b)(2) from 45 CFR part 46 requirements.

February 16, 2016

Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?

- YES

- Research is not eligible for exemption under 45 CFR 46.101(b)(2).

- NO

- Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?

From Chart 2

Does the research involve only** the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *

("Existing" means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

YES

Are these sources publicly available?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

NO

NO

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES

Return to Chart 2 and consider whether 45 CFR 46.101(b)(5) exemption applies

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/index.html, and on coded data or specimens at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html for further information on those topics.
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

From Chart 2

Is the research or demonstration project conducted or approved by the Department or Agency Head?

- YES
  - Does the research or demonstration project involve **only** the study, evaluation, or examination of:
    - Public benefit or service programs:
      - YES
        - Research is eligible for exemption under 45 CFR 46.101(b)(5) from 45 CFR part 46 requirements.*
      - NO
        - Procedures for obtaining benefits or services under public benefit or service programs:
          - YES
            - Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs:
              - YES
                - Possible changes in **methods or levels of payment** for benefits or services under those public benefit or service programs?
                  - YES
                    - Research is not eligible for exemption under 45 CFR 46.101(b)(5).
                  - NO
                    - Return to Chart 2 and consider whether 45 CFR 46.101(b)(6) exemption applies.
              - NO
                - NO
                  - Return to Chart 2 and consider whether 45 CFR 46.101(b)(6) exemption applies.
          - NO
            - NO
              - NO
                - NO
                  - Return to Chart 2 and consider whether 45 CFR 46.101(b)(6) exemption applies.

- NO
  - Return to Chart 2 and consider whether 45 CFR 46.101(b)(6) exemption applies.

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.


February 16, 2016
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

From Chart 2

Does the research involve only** a taste and food quality evaluation or a food consumer acceptance study?

YES

Are wholesome foods without additives consumed?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(6) from 45 CFR part 46 requirements.

Other Federal, State, and local laws and/ or regulations may apply to the activity. [45 CFR 46.101(f)]

NO

Is food consumed that contains a food ingredient, 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 U.S. Department of Agriculture?

YES

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(6).

Go to Chart 8

February 16, 2016

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

From Chart 2, or 7

Has the research been previously reviewed and approved by the IRB? YES→ Is the review a continuing review? [45 CFR 46.109(d)]

NO→ Does the research present no more than minimal risk to human subjects and does the research involve only procedures included in categories 1 through 7 on the list of categories of research that may be reviewed through an expedited review procedure? [45 CFR 46.110(b)(1)]

YES→ Is the research classified? [Paragraph (D) of Categories of Research That May Be Reviewed By an IRB through an Expedited Review Procedure.]

NO→ Review by convened IRB is required.

Does the review involve a minor change in approved research during the (one year or less) period of approval? [45 CFR 46.110(b)(2)]

YES→ Are measures in place to make risks no more than minimal?

NO→ Go to Chart 10

YES→ Go to Chart 9

Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging? [Paragraph (C) of Categories.]

Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution’s or IRB’s use of the expedited review procedure. [45 CFR 46.110(d)]

February 16, 2016

Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?


From Chart 8

Has the research been previously reviewed and approved by the IRB using expedited procedures?

YES → Have conditions changed such that the research is no longer eligible for expedited review (e.g., protocol change, or experience shows research to be of greater than minimal risk)?

YES → Review by convened IRB is required.

NO → Have conditions changed to make the research eligible for expedited review under the applicability criteria and categories 1 through 7 on the list of categories that may be reviewed by expedited procedures (e.g., research is within those categories and experience confirms research to be of no greater than minimal risk)?

[45 CFR 46.110(a)]

YES → Research is eligible for IRB review through expedited procedures.

NO → Go to Chart 10

NO → Category 8

(a) For this site: Is the research permanently closed to enrollment of new subjects? and Have all subjects completed all research-related interventions? and Does the research at this site remain active only for long-term follow-up of subjects?

YES → Category 9

(b) Have no subjects been enrolled at this site? and Have no additional risks been identified anywhere?

YES → (c) Are the remaining research activities at this site limited to data analysis?

NO → NO → Category 9

Has the IRB determined and documented at a convened meeting that the research involves no greater than minimal risk?

YES → Is the research conducted under an IND or IDE?

February 16, 2016
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?

**Note:** If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. (See 45 CFR 46.408(c))

From Chart 8 or 9

1. Will the research or demonstration project be conducted by or subject to the approval of state or local government officials? [45 CFR 46.116(c)(1)]
   - YES
   - NO

2. Will the research involve greater than minimal risk as defined in Section 46.102(i)? [45 CFR 46.116(d)(1)]
   - YES
   - NO
   - NO

3. Is it practicable to conduct the research without the waiver or alteration? [45 CFR 46.116(d)(3)]
   - YES
   - NO

4. Will waiving or altering the informed consent adversely affect the subjects’ rights and welfare? [45 CFR 46.116(d)(2)]
   - YES
   - NO

5. Will pertinent information be provided to subjects later, if appropriate? [45 CFR 46.116(d)(4)]
   - YES
   - NO

6. If informed consent is not waived entirely
   - NO

7. Is the project designed to study, evaluate, or otherwise examine:
   - (i) Public benefit of service programs;
   - (ii) procedures for obtaining benefits or services under those programs;
   - (iii) possible changes in or alternatives to those programs or procedures; or
   - (iv) possible changes in methods or levels of payment for benefits or services under those programs? [45 CFR 46.116(c)(1)]

   - YES
   - NO

8. No waiver of informed consent or alteration of consent elements is allowed.

   - YES
   - NO

   Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.


February 10, 2016
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

From Chart 10

Would the consent document be the only record linking the subject and the research and would the principal risk be potential harm resulting from a breach of confidentiality?
[45 CFR 46.117(c)(1)]

NO

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context?
[45 CFR 46.117(c)(2)]

YES

IRB may waive the requirement for a signed consent form for some or all subjects.

NO

IRB may NOT waive the requirement for a signed consent form for any subjects.

YES

If IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

Investigator will ask each subject if he or she wants documentation linking the subject with the research.
[45 CFR 46.117(c)(1)]

AND

IRB may require investigator to provide subjects with a written statement regarding the research.
[45 CFR 46.117(c)]

AND

Subject’s wishes will govern whether informed consent is documented.
[45 CFR 46.117(c)(1)]

END
Quick Links

- FDA Regulations Protecting Human Subjects [http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118893.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118893.htm)
- NIH Human Subjects Protections Training [https://humansubjects.nih.gov/resources](https://humansubjects.nih.gov/resources)
- Electronic Code of Federal Regulations Title 45 → Subtitle A → Subchapter A → Part 46 [https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitr=20180719&n=pt45.1.46&r=PART&ty=HTML](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitr=20180719&n=pt45.1.46&r=PART&ty=HTML)

For SCDMH Employees: