



Commissioner's Policy Statement and Implementing Procedures

SUBJECT:	Institutional Review Board Policy
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REFERENCES:	DHHS - 45 CFR 46 Protection of Human Subjects FDA - 21 CFR 50 & 56 Protection of Human Subjects & Institutional Review Boards DHHS - 45 CFR 160 & 164 Standards for Privacy of Individually Identifiable Health Information
FORMS AND ATTACHMENTS:	CT.gov portal/DMHAS/Divisions & Offices/Institutional Review Board

STATEMENT OF PURPOSE: The purpose of this policy is to specify the manner in which research proposals will be reviewed, overseen and acted upon; in order to protect the rights and welfare of human research subjects participating in Department of Mental Health and Addiction Services (DMHAS) sponsored or approved research; and in order to comply with federal regulations regarding the protection of human subjects.

POLICY: Compliance with Department of Health and Human Services (DHHS) regulations (Federal Policy for the Protection of Human Subjects, known as the Final Rule) is required whenever DMHAS becomes engaged in human subjects research conducted or supported by any federal department or agency that has adopted the Final Rule, unless the research is otherwise exempt from the requirements of the Final Rule or a Federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance. Compliance with Food and Drug Administration (FDA) regulations is required when research involves products regulated by the FDA.

DHHS regulations relating to the protection of human subjects are codified at Title 45 CFR Part 46 and are enforced by the Office of Human Research Protection (OHRP). The FDA regulations are codified at Title 21 CFR Part 50 & 56 and are enforced by the FDA. In large part, the FDA regulations mirror 45 CFR 46 with some differences. Research conducted or sponsored by DMHAS facilities most often falls under the jurisdiction of DHHS, but in the event of dual jurisdiction, both regulations apply. Questions related to this policy may be directed to the DMHAS IRB chair at any time.

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III. JURISDICTION OF DMHAS IRB

The DMHAS Office of the Commissioner (OOC) Institutional Review Board (IRB) has jurisdiction over review and approval of activities categorized as research involving human subjects when DMHAS is engaged in the research.

The DMHAS IRB will review, prospectively and on a continuing basis, all research involving human subjects where the research is either sponsored by or conducted at DMHAS. The DMHAS IRB is responsible and has authority to approve research, require modifications, disapprove research and suspend or terminate approval.

NOTE: Because the Connecticut Mental Health Center (CMHC) is jointly operated by both DMHAS and Yale University, proposals for research to be conducted at CMHC are reviewed and approved by the Yale Human Investigations Committee unless the research will also be conducted at another DMHAS facility.

Research that has been reviewed and approved by the IRB may be subject to further review by the Commissioner or designee. However, another DMHAS body may not approve a research proposal that has been disapproved by the IRB.

IV. REVIEW OF RESEARCH PROPOSALS NOT SPONSORED BY DMHAS OOC THAT INVOLVE DMHAS FACILITIES AND/OR CLIENTS

Research proposals not sponsored by DMHAS OOC that involve DMHAS facilities and/or clients must undergo a multi-stage review process. This includes proposals submitted by investigators who are 1) not under contract to DMHAS to conduct research; 2) DMHAS staff outside of OOC; and 3) DMHAS employees whose research is related to educational requirements. See *Commissioner's Policy 8.2 Review of Research Proposals Not Sponsored by DMHAS OOC that Involve DMHAS Facilities and/or Clients* for information about this multi-stage review process.

When DMHAS reviews research as described above, the review and findings of the IRB will generally apply the Final Rule regulations and DMHAS IRB policy in the same manner as with all other research. However, review and subsequent IRB actions in such cases are subject to flexibility as deemed appropriate by the IRB.

V. DEFINITIONS

Definitions for the purpose of this policy (45 CFR 46.102):

Engagement in human subjects research: OHRP considers an institution engaged in human subjects research¹ when its employees or agents, for the purposes of a research project, obtain: (1) Data about the subjects of the research through intervention or interaction with them; (2)

¹ Engagement of Institutions in Human Subjects Research (2008) <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

Identifiable private information about the subjects of the research; or (3) The informed consent of human subjects.

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

- Obtains information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens 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.

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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

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

VI. TYPES OF IRB REVIEW

A. Non-Research Determination

Certain projects do not constitute research as defined in 45 CFR §46.102(1). Investigators must submit the research proposal to the IRB to determine whether or not the activity is research. The chair or designee determines if activity is not research and may use their discretion as to whether the research will be reviewed by the convened IRB. The chair, designee or the convened IRB may request changes or clarifications before a non-research determination is made.

Investigators are expected to adhere to ethical principles for non-human subject research projects and to respect and protect to the extent possible the privacy,

confidentiality, and autonomy of participants. All applicable State privacy laws must be followed.

Although a proposal may not constitute research involving human subjects, informed consent may be appropriate. Information conveyed in an informed consent process should address all applicable required elements of informed consent.

Non-research studies using protected health information (PHI) must follow HIPAA regulations for authorization and confidentiality protections, including projects using PHI about non-living individuals. Below are additional forms that may be needed for these projects:

B. Exempt Determination

Certain categories of research are exempt from 45 CFR 46 regulations. Although the regulations do not require that someone other than the investigator be involved in making a determination that a research study is exempt, because of the potential for conflict of interest in this situation, federal guidance recommends that investigators not be given the authority to make an independent determination that their research is exempt.

Investigators must submit the research proposal to the IRB to determine if the research is exempt from the regulations. The chair or designee determines if proposed research is exempt in accordance with regulations included in 45 CFR 46.101(b) and may use their discretion as to whether the research will be reviewed by the convened IRB. The chair, designee or the convened IRB may request changes or clarifications before a finding of exemption is granted.

Although research may be exempt from the regulations, informed consent may be appropriate. Information conveyed in an informed consent process should address all applicable required elements of informed consent.

C. Convened IRB Review

When the convened IRB reviews a research proposal, a quorum of members must be present, including a member whose primary interest is in the non-scientific area.

D. Expedited Review

Expedited review is conducted by the chair or another designated IRB member outside of a convened meeting. The chair or designee will determine if the proposed research is appropriate for expedited review in accordance with regulations included in 45 CFR 46.110 and 21 CFR 56.110. The reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove a proposal; a research activity may be disapproved only after convened IRB review.

VII. INITIAL AND CONTINUING REVIEW OF RESEARCH; FINAL REPORT

A. Convened IRB Review Procedures

1. Documentation investigators must submit to the IRB for initial review
 - a. Completed *DMHAS Application for IRB Approval*
 - b. Documentation of education in the protection of human subjects for all key personnel involved in the conduct of the study, if applicable
 - c. IRB approval letters from other institutions
 - d. Informed consent form(s) and/or information sheet(s)
 - e. Request for waiver or alteration of consent, if applicable
 - f. Any other form/material that prospective participants will see or be asked to sign such as release of information forms, future contact form, consent to audio tape, etc.
 - g. All recruitment materials that prospective participants will see or hear such as posters, flyers, media announcements, etc.
 - h. Scripts used to guide verbal recruitment
 - i. All surveys or questionnaires given or administered to participants such as diagnostic tools, questionnaires, surveys, etc.
 - j. Data collection form, if applicable

All materials must be submitted in Microsoft® Word via email.

2. Documentation investigators must submit to the IRB for continuing review:
 - a. Completed *DMHAS Application for Continued Approval*
 - b. IRB approval letters from other institutions
 - c. Approved informed consent form(s) and/or information sheet(s)
 - d. Other approved documents that participants see or are asked to sign such as a release of information form, future contact form, consent to audio tape, etc.
 - e. All approved recruitment materials that prospective participants see or hear such as posters, flyers, media announcements, etc.
 - f. Approved scripts used to guide verbal recruitment

All materials must be submitted in Microsoft® Word via email

3. Documentation investigators must submit to the IRB for final report upon completion of research
 - a. The investigator must submit a final report to the IRB upon completion of the research project using the *Application for Continued Approval/Final Report* form.
 - b. The research is considered completed when the following occurs:

- i. No additional participants are being enrolled and,
- ii. All intervention with participants has ended, and
- iii. Data analysis is complete and/or all identifiable data has been de-identified, and
- iv. All other research related activity has ended.

All materials must be submitted in Microsoft® Word via email

4. Reviewer system used by the convened IRB

a. Initial Review

The DMHAS IRB uses an initial screening process, during which the IRB chair reviews each submission for clarity, completeness and compliance with human subjects protection regulations. The IRB chair may ask for modifications or clarifications to the submission before it is reviewed by the convened IRB.

All IRB members will receive copies of the documents listed in Section A1 above. Where interview or other instruments consist of many pages the chair may choose to omit them from the materials distributed to IRB members. In such cases the chair will review the materials; provide a general description of the materials to the board; and will also make them available to board members and at the meeting during which the study will be reviewed.

b. Continuing Review of research where DMHAS is engaged

The DMHAS IRB uses an initial screening process for continuing reviews, during which the IRB chair reviews each submission for completeness and compliance. The IRB chair may ask for modifications or clarifications to the submission before it is reviewed by the convened IRB.

The IRB chair will determine at this time if continuing review is no longer required because the research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study;

- i. Data analysis, including analysis of identifiable private information or identifiable biospecimens; or
- ii. Accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.

Where the research requires continuing review by the convened IRB, all members will receive copies of the documents listed in Section A2 above. Where changes are being proposed that would be reflected in the approved protocol the IRB members will receive a copy of the revised protocol. If there

are no changes to the currently approved protocol, the IRB chair will review the protocol and will distribute to IRB members when in the opinion of the chair it would be helpful for members to re-review the entire protocol.

c. Continuing review of research where DMHAS is not engaged

At the time of continuing review of research, where DMHAS is not engaged in the research, there are occasions where the status of DMHAS clients is very different from the status of other research participants who were enrolled from different sites. In such cases the DMHAS IRB may conduct an expedited review where the criteria for expedited continuing review applies to DMHAS participants, but not necessarily to other participants. Specifically, the DMHAS IRB may conduct an expedited review of research previously approved by the convened IRB as follows:

- i. Where (i) the research is permanently closed to the enrollment of DMHAS participants; (ii) all DMHAS clients have completed all research related interventions; (iii) and the only remaining activity with respect to DMHAS clients would be long term follow up. These criteria would apply even if other participants from unaffiliated institutions are still active participants; and even if the institution engaged in the research conducts their own ongoing review.
- ii. Where no DMHAS clients have been recruited or enrolled in the study and where no additional risks have been identified (no adverse events, no complaints, no additional information/literature has suggested a change in risk since initial approval). These criteria would apply even if participants from other unaffiliated institutions have been recruited or enrolled; and even if the institution engaged in the research conducts their own ongoing review.
- iii. Where the remaining research activity related to DMHAS participants is limited to data analysis. These criteria would apply even if other participants recruited from other institutions are still actively involved in research activities; and even if the institution engaged in the research conducts their own ongoing review.

5. Range of possible actions the convened IRB can take

a. Initial Review

- i. Approve with no modifications being requested
- ii. Approve contingent upon specific modifications being made*
- iii. Defer action pending modifications and/or clarification.
- iv. Disapprove.

- b. Continuing review
 - i. Approve with no modifications being requested
 - ii. Approve contingent upon specific modifications being made
 - iii. Suspend approval pending receipt of additional information or upon receipt of modifications*
 - iv. Terminate approval (see below under Suspension or Termination of IRB Approval).

*When the IRB stipulates specific and unambiguous changes that require simple concurrence by the investigator and are unlikely to require further review, the chair or another designated member may review changes outside of a convened meeting as outlined above under Initial Review.

6. Format of a convened meeting

- a. The IRB will convene monthly or at intervals sufficient to review new research proposals, monitor ongoing studies and conduct the ongoing business of the IRB.
- b. Minutes will be sent to members sufficiently in advance of the meeting to allow adequate time for review prior to the meeting. Minutes will be formally approved at convened meetings.
- c. If the proposed research is reviewed by the convened IRB, materials will be distributed to IRB members sufficiently in advance of the meeting to allow adequate time for review prior to the meeting.
- d. Members may attend a convened meeting of the IRB either in person or by teleconference. Members participating via teleconference are included as part of the quorum. Whether attending in person or by phone, members who have received and reviewed materials related to the study(ies) under review may participate in deliberations and may vote.
- e. Each member uses checklists to ensure that the review is comprehensive and copies of the completed checklists are kept with the file. These checklists are:
 - i. Checklist - Expedited Review
 - ii. Checklist - Non Research Determination
 - iii. Checklist - Exempt Determination
 - iv. Checklist - Initial Application (includes criteria for approval and for informed consent)
 - v. Checklist - Child Participation
 - vi. Checklist - Prisoner Participation
 - vii. Checklist - Continuing Approval

- f. Attendance sheets will be signed to document attendance or if meetings are conducted by teleconference, participation will be documented by the chair. Minutes of the meeting will also reflect which members attended in person and which participated via teleconference.
- g. Members who will be absent from a meeting may submit their comments related to studies under review. These comments will be shared with the convened IRB; however the absent member may not vote.
- h. When deemed necessary, the IRB may invite individuals with expertise and knowledge in specialized areas for the purpose of providing consultation and opinion regarding a proposal. However, these individuals may not vote.
- i. The principal investigator or their designee will be invited to attend the IRB meeting, in person or via teleconference, in order to respond to questions raised by IRB members. The principal investigator or their designee cannot be present during the IRB's final discussion and vote.

7. Defining and maintaining quorum and the process followed if quorum is lost

A quorum is achieved when a majority of members are in attendance. When the IRB consists of an unequal number of members, the quorum is determined by dividing the number of members by two and rounding up by one, e.g., if there are 5 members a quorum is reached with 3 members present. If the IRB consists of an even number of members the quorum is determined by dividing the number of members by two and adding one, e.g., if there are six members a quorum is reached with four members present. Once a quorum has been achieved issues can be decided based upon majority vote. Non-expedited research proposals may only be voted upon at a convened meeting where there is a quorum and where attendance includes one member whose primary interest is in non-scientific areas. If a quorum is lost during the meeting no further action (voting) may be taken in relation to the studies under review. Minutes of the meeting should reflect loss of the quorum and the reason for the loss, e.g., early departure, etc.

8. Managing IRB members/alternates with conflicting interests

Members will attest to a lack of conflict of interest for each research proposal that they review and vote on by signing a Conflict of Interest Declaration. An IRB member who has a conflict of interest related to a study under review may not participate in the review other than to provide information about the proposal. A member with a conflict of interest is not required to leave the room during final discussion and vote; but may leave the room depending on the degree of conflict as reported by the member with the conflict, the comfort of the IRB member with the conflict and the opinion of the IRB. Members with a conflict of interest will recuse themselves from the vote.

B. Expedited review procedures

1. Documentation investigators must submit to the IRB for initial review

The same documents that are submitted for review by the convened IRB must be submitted for expedited review process

All materials must be submitted in Microsoft® Word via email

2. Reviewer system used for expedited review

IRB chair conducts all expedited reviews. The chair uses checklists to ensure that the review is comprehensive and copies of completed checklists are kept with the file. These checklists are:

- a. Checklist - Expedited Review
- b. Checklist - Non Research Determination
- c. Checklist - Exempt Determination
- d. Checklist - Initial Application (includes criteria for approval and for informed consent)
- e. Checklist - Child Participation
- f. Checklist - Prisoner Participation
- g. Checklist - Continuing Approval

The IRB chair will determine at this time if continuing review of research is not required due to the following circumstances:

- a. The research will be eligible for expedited review
- b. The research will be reviewed by the IRB in accordance with the limited IRB review described in 45 CFR 46.104(d)(2)(iii) or (d)(3)(i)(C)

2. Range of possible actions the expedited reviewer can take

- a. Approve with no modifications being requested
- b. Approve contingent upon specific modifications being made
- c. Defer action pending modifications and/or clarification

3. Method used for keeping all IRB members advised of research proposals approved via expedited review

The chair will prepare a *Monthly Report of IRB Activity*, which includes expedited reviews conducted and any other activity that would routinely be contained within the IRB Agenda and/or IRB Minutes. There is no specified time frame for completing this report, but it will generally be forwarded to IRB members before the next regularly scheduled meeting. Reports of IRB Activity are not approved

by the IRB, but IRB members are free to pose questions, make comments and/or raise issues about topics covered in the report.

C. Criteria for IRB approval of research

1. Risks to human subjects are minimized:
 - a. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
 - b. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.
5. Informed consent will be appropriately documented or appropriately waived in accordance with 45 CFR 46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

D. Requirements for informed consent form and informed consent process

The informed consent form is carefully reviewed to ensure that it aligns with the research protocol and contains all applicable elements of informed consent.

1. General requirements for informed consent

- a. Before involving a human subject in research covered by this policy, the investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
- b. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- c. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
- d. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- e. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- f. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
- g. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

2. Basic elements of informed consent

In seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

- a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- b. A description of any reasonably foreseeable risks or discomforts to the subject;
- c. A description of any benefits to the subject or to others that may reasonably be expected from the research;
- d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- f. 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;
- g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- i. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

- ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
 - j. When a study falls under the jurisdiction of the DHHS and/or the FDA, a statement noting the possibility that the DHHS and/or the FDA may inspect the research records must also be included.
3. Additional elements of informed consent, if applicable

One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

- a. 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) that are currently unforeseeable;
- b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
- c. Any additional costs to the subject that may result from participation in the research;
- d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- e. 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;
- f. The approximate number of subjects involved in the study;
- g. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- h. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions; and
- i. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

4. Translation of the informed consent form for non-English speaking participants
 - a. Minimal risk studies: Studies that are eligible for expedited review require translation of the consent/assent forms. The IRB will accept documents translated by an individual fluent (i.e., can speak, read and write) in a given language.
 - b. Greater than minimal risk studies: A professional translation of the consent/assent form(s) and recruitment material(s) is required for studies that pose more than minimal risk to subjects (i.e., studies that require convened IRB review), unless the IRB has granted a waiver of documentation of informed consent.

For a professional translation, the investigator must provide the qualifications of the individual who translated the informed consent documents and recruitment materials. Include any credentials, certifications, education, native language fluency, etc.

5. Requirements for waiver or alteration of consent

If the investigator wishes to request a waiver of any informed consent requirement they must submit an *Application for Waiver or Alteration of Consent*. The IRB chair and/or convened IRB will evaluate the waiver application within the limits of the applicable regulations.

6. Requirements for waiver of documentation of consent

If the investigator wishes to request a waiver of any informed consent requirement they must submit an *Application for Waiver of Documentation of Consent*. The IRB chair and/or convened IRB will evaluate the waiver application within the limits of the applicable regulations.

7. Requirements related to the HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act (HIPAA) issued the Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”). The Privacy Rule establishes conditions under which certain groups and organizations covered by the rule can use or disclose individually identifiable health information (Protected Health Information). The Privacy Rule requires that individuals generally be given an opportunity to agree to the use and disclosure of their protected health information by signing an authorization form. This authorization requirement applies to research subjects unless an IRB or Privacy Board approves a waiver of the Authorization requirement.

Although the Privacy Rule does not require an IRB or privacy board to review the HIPAA authorization covering the use of protected health information, the

DMHAS IRB will review such authorizations as part of the overall review and approval process. This authorization is also referred to as Release of Information or ROI.

The Privacy Rule does require that an IRB or Privacy Board review and approve requests for a waiver of the HIPAA authorization requirement. The DMHAS IRB is the body responsible for reviewing, approving and documenting waiver of the HIPAA authorization requirement when use or disclosure of protected health information is for research purposes at DMHAS.

To request a waiver of the HIPAA authorization requirement, the investigators must submit an *Application for Waiver of HIPAA Authorization Requirements*. The IRB chair and/or convened IRB will review the waiver application within the limits of the applicable regulations. The Privacy Rule is codified at 45 CFR Parts 160 and 164).

8. Requirements related to Certificates of Confidentiality

Certificates of Confidentiality are issued to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the Federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. Examples are information related to use of alcohol or other substance use, illegal behavior, sexual behavior, or other information that, if revealed, could potentially be damaging to the participant. When such identifiable information is collected and recorded during the course of a study, the IRB suggests that the investigator consider applying for a Certificate of Confidentiality.

The Certificate of Confidentiality is not intended to protect researchers from reporting information regarding child abuse, elder abuse or the threat of harm to self or others if revealed by a study participant.

Where application for a Certificate of Confidentiality will be made, study participants must be informed at the time of the informed consent process, of the accurate status of the application, e.g., it has either been applied for or has been obtained.

The investigator is responsible for promptly documenting to the IRB receipt of the Certificate of Confidentiality.

E. Safeguards to protect the rights and welfare of vulnerable subjects

Inclusion of certain vulnerable populations in research requires specific additional protections. The IRB will closely review research proposals that involve participants who are vulnerable to coercion or undue influence, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons to ensure that safeguards are included to protect the rights and welfare of these subjects.

F. Additional protections for pregnant women, human fetuses and neonates; for prisoners; and for children

For HHS-conducted or -supported research where these populations are involved, each member of the IRB will use of a checklist to ensure that the required protections are satisfied. The specific protections are found under 45 CFR 46 Subpart B, 45 CFR 46 Subpart C, and 45 CFR 46 Subpart D respectively.

G. Qualifications of the investigator(s) and study staff

Investigators have the primary responsibility for protecting the rights and welfare of human research subjects and are responsible for complying with all applicable provisions of the Final Rule. Investigators and study staff must be qualified by education, training, and experience to properly conduct research. Investigators and study staff must know the regulatory requirements for the protection of human research subjects and have reviewed this policy.

Federal guidelines require that the IRB obtain documentation of such training from research investigators as a condition for conducting research involving human subjects. The IRB chair will document receipt and acceptance of such training before IRB approval is granted. At any point during the course of a study, if deemed necessary, the IRB may require that the investigator and/or other research staff obtain additional training.

H. Determining and documenting effective date of initial approval and continuing review

1. Effective date of initial IRB approval

- a. If the convened IRB reviews and approves a research proposal without need for modifications or clarifications, the effective date of initial IRB approval will be the date of the convened IRB meeting.
- b. If the convened IRB requests modifications or clarifications and the investigator's response satisfy the IRB's request and raise no further questions, the effective date of initial IRB approval will be the date that the modifications were reviewed.

- c. If the research proposal is subject to expedited review, the effective date of initial IRB approval will be the date that the chair approves the research.

2. Effective date of continuing approval

Continuing review of research requiring review by the convened IRB will take place at intervals appropriate to the degree of risk, but not less than once per year. The effective date of continuing review will be a minimum of one year from the date of initial approval.

- I. Communicating the IRB's findings and actions to investigator and institution

1. Communicating the IRB's findings and actions to the investigator

A letter containing IRB comments or approval or of the IRB members will be sent to the investigator within two business days after the review. The letter will contain any modifications or clarifications required by the IRB as a condition of approval. When changes are minor and/or few in number the chair or designee may convey the requested changes to the investigator verbally. Regardless of how the requested changes are communicated to the investigator, they will also be documented in the IRB minutes.

When the IRB stipulates specific and unambiguous changes that require simple concurrence by the investigator and are unlikely to require further review, the members may vote to allow the chair or another designated member to review the modifications outside of a convened meeting.

2. Communicating the IRB's findings and actions to the institution

- a. Where recruitment or other research activities occur at a state-operated facility, the DMHAS IRB chair will send one of the following documents to the respective facility officials, as appropriate:

- i. *Notice of Initial IRB Approval*

- A copy of the approved IRB application
- A copy of the approved informed consent form

- ii. *Notice of Continuing Approval*

- iii. *Notice of Non-Research Determination*

- iv. *Notice of Exempt Determination*

- v. *Notice of Study Closure or that recruitment and/or all research activity has ended at the facility*

- vi. *Notice of Expiration of Approval*

- vii. *Notice of Suspension or Termination of IRB Approval*

The institutional official may also initiate communication with at any time if there are any questions or concerns regarding conduct of a study within their facility.

- b. Where DMHAS has an Authorization Agreement with another institution for the DMHAS IRB to conduct review and oversight of the other institution's research, or where DMHAS has extended its Federalwide Assurance to an Institution or Independent Investigator, the DMHAS IRB chair will send one of the following documents to the institution, as appropriate:
 - i. *Notice of Initial IRB Approval*
 - A copy of the approved IRB application
 - A copy of the approved informed consent form
 - ii. *Notice of Continuing Approval*
 - iii. *Notice of Approval of Revision*
 - iv. *Notice of Study Completion*
 - v. *Notice of Expiration of Approval*
 - vi. *Notice of Suspension or Termination of IRB Approval*
3. Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval

If the investigator's response to any required modifications or clarifications responds to the IRB's request and raise no further questions, the chair will issue a Notice of Approval. Where the modifications do not respond to the IRB's request or where further questions arise, the study will be scheduled for further discussion at the next convened IRB meeting.

4. Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond

Only the convened IRB can disapprove a research proposal. The decision to disapprove a proposal will be communicated via a written Notice of IRB Disapproval, which will include the date of IRB review and the basis for disapproval.

The investigator may submit a letter in response to the reason(s) for the disapproval which will be reviewed at the next convened IRB meeting.

VIII. FREQUENCY OF IRB REVIEW; VERIFICATION REGARDING REVISIONS

- A. Determining the approval period/continuing review interval for the proposed research
 1. General criteria used to make a determination of the review interval

- a. Continuing review of research must be conducted at least once annually, but may occur more frequently at the discretion of the IRB. At the time of initial approval, the primary factor to be considered when determining the continuing review schedule is the level of risk involved. Related factors to be considered may include type of intervention being proposed; issues related to the study population; or other issues as deemed relevant by the IRB.
 - b. At any point while still an active study under the jurisdiction of the IRB, the IRB may modify the schedule for continuing review to become more or less frequent (but never less frequently than annually). A change in review schedule may be based upon changes in the procedures, changes in the level of risk, the occurrence of complaints or injuries related to the research, other adverse incidents, report or discovery of protocol deviations, report or discovery of unapproved changes in protocol, concern regarding adherence to the approved protocol, or other factors as deemed relevant by the IRB.
2. Documenting the approval period/continuing review interval

The initial approval period and continuing review interval are documented three ways:

- a. In the minutes of the convened IRB meeting or, for expedited review, in the *Monthly Report of IRB Activity*
 - b. In the *Notice of Initial IRB Approval* and *Notice of Continuing Approval* sent to the investigator
 - c. Each study document is stamped with the approval period
3. Communicating the IRB's determinations regarding the approval period/continuing review interval

The investigator will be notified of the approval expiration date and the timeframe for submitting a Continuation Application at the time of initial approval and at least six weeks prior to the approval expiration date. However, it is ultimately the responsibility of the investigator to submit the application in a timely manner. IRB approval cannot be extended without review and approval of the application. In the event that continued approval is not granted by the expiration date, all research related activity must cease until continued approval is granted. The only exception would be when termination of research activity would potentially be harmful to the participants. In such a case the IRB would consider the specific situation and together with the investigator arrive at an appropriate plan of action.

- B. Determining whether verification from a source other than the investigators is required

The IRB may also request verification from a source other than the investigators that no material changes have occurred in the procedures since the previous IRB approval.

A request for such verification may be based upon the occurrence of complaints or injuries related to the research, other adverse incidents, report or discovery of protocol deviations, report or discovery of unapproved changes in protocol, concern regarding adherence to the approved protocol, or other factors as deemed relevant by the IRB. However, it is ultimately the responsibility of the investigator to submit the application in a timely manner.

IX. REQUESTING PROPOSED CHANGES TO THE IRB; PRIOR IRB REVIEW AND APPROVAL OF CHANGES

A. Changes in approved research proposed by the investigator

IRB approval must be obtained prior to the implementation of any revision in the approved research proposal or other study documents. In order to obtain approval for a proposed change in previously approved proposal or study documents, the investigator must submit the following information:

- *Application for Approval of Revision* outlining the proposed revisions and reason(s) for the change
- A copy of any approved document(s) for which a change is requested, with changes clearly identified
- A copy of any changed document(s) with the changes made, which will be used for stamping approval

All materials must be submitted in Microsoft® Word via email

B. Reviewer system used for proposed changes in approved research

A proposed change to approved research study will generally be reviewed at the same level of review in which the research was first reviewed, either by the expedited review process or by the convened IRB.

1. Expedited review of proposed changes

If the research required convened IRB review at the initial or last continuing review, but the proposed change is minor, the review may be conducted using an expedited review procedure. Requests for proposed changes may be eligible for expedited review if the study was eligible for expedited initial review or the changes are minor and do not represent a material change in the research. The DMHAS IRB defines minor as:

- a. Changes that do not materially increase risk;
- b. Changes that do not materially decrease benefit; or
- c. Changes that do not materially decrease scientific merit.

Examples of minor changes are:

- a. Adding a new procedure that is on the expedited list and involves no more than minimal risk.
- b. Adding a new minimal risk procedure that procedure is not on the expedited list, e.g., an additional minimal risk questionnaire
- c. Making a minor change to research that is not on the expedited list, but does not involve the addition of a procedure, such as:
- d. Change in the equally qualified individuals who will do statistical analysis.
- e. Change in consent form wording that does not increase risk or decrease benefit. For example, changing “nausea” to “nausea and stomach upset,” or making grammatical corrections.
- f. Replacing old forms with essentially equivalent new forms, and the change is noted in a revised protocol.
- g. Changing the order of questions in a study questionnaire.

The IRB chair will conduct expedited reviews of proposed change to the research using a *Checklist - Revision Application* to ensure that the review is comprehensive and copies of completed checklists are kept with the file.

2. Convened IRB review of proposed changes

Convened IRB review will be conducted for research that was initially reviewed by the convened IRB and where major changes are proposed. The DMHAS IRB defines major change as:

- a. Major change in the design or goal of the study
- b. Making multiple changes in the protocol, instruments, and/or consent
- c. Adding a new consent form
- d. Expanding the eligibility criteria
- e. Increasing the number of participants at risk
- f. Adding questions asking for sensitive information e.g. depression or sexuality
- g. Adding an element that may breach the confidentiality of the participant (example: adding focus groups)

Each IRB member will conduct a review of proposed change to the research using a *Checklist - Revision Application* to ensure that the review is comprehensive and copies of completed checklists are kept with the file.

C. Communicating the IRB’s findings and actions for proposed changes in approved research to investigator and institution

The IRB chair will provide written notice to the investigator, and others as necessary, of the IRB action taken. Where applicable, the investigator will be asked to incorporate approved changes into the written protocol.

X. REPORTING OF UNANTICIPATED PROBLEMS, SERIOUS OR CONTINUING NONCOMPLIANCE, AND ANY SUSPENSION OR TERMINATION OF IRB APPROVAL

Federal Regulations (45 CFR 46.103(b)(5)) require prompt reporting to the IRB, appropriate institutional officials, and the federal department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

A. Identifying who is responsible for promptly reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA any:

1. Unanticipated problems involving risks to human subjects or others

The investigator is responsible for reporting any unanticipated problem involving risk to human subjects or others, including an adverse event, protocol deviation, or study related complaint related to the conduct of the research.

2. Serious or continuing noncompliance

An initial report of non-compliance might be reported by the principal investigator, research staff, study participants, others, or discovered through IRB audit or ongoing review.

The IRB chair will report incidents of serious or continuing non-compliance to the DMHAS IRB Signatory Official, Research Director and the site(s) where the research is being conducted. The chair will also notify the appropriate agency when the research is federally funded, as well as OHRP and the FDA as appropriate.

3. Suspension or termination of IRB approval

The IRB chair is responsible for reporting suspension or termination of IRB approval to the investigator, the DMHAS IRB Signatory Official, the Research Director and the site(s) where the research is being conducted. The chair will also notify the appropriate agency when the research is federally funded, as well as OHRP and the FDA as appropriate.

B. Reviewing information about unanticipated problems involving risks to human subjects or others

1. What might qualify as an unanticipated problem involving risks to human subjects or others

- a. Adverse events
 - i. *Anticipated adverse event* is defined as an experience or reaction related to the conduct of the research that is identified or outlined in the research procedure and the informed consent form. Anticipated adverse events will be reported at the time of the continuing review.
 - ii. *Unanticipated adverse event* is defined as an experience or reaction related to the conduct of the research that is not identified or outlined in the research proposal and the informed consent form, including a change in the nature, severity or frequency of the experience or reaction from what was outlined in the research procedure; and/or any unanticipated problem associated with the conduct of the research related to the level of risk to the participants. The investigator must report unanticipated adverse events in writing to the IRB within 7 business days of occurrence.
 - iii. *Serious adverse event* includes, but is not limited to one that results in death; is life threatening or potentially life-threatening; results in disability; results in hospitalization or other significant and unanticipated treatment; or other events deemed to be serious by the investigator. The investigator will report serious adverse events within 3 days. If reported by phone a written report must follow within 5 business days.
 - b. A protocol deviation is defined as a change in the protocol that has not been reviewed and approved by the IRB. Whether the protocol deviation is made intentionally to meet the immediate needs of an individual participant or situation or unintentionally in error, the protocol deviation must be reported to the IRB if the deviation is deemed as having the potential to increase the risk to the participant.
 - c. A study related complaint is defined as a formal expression of dissatisfaction or an allegation of wrongdoing, related to the conduct of research, made by a research participant or other(s). A complaint may be expressed verbally or in writing and may be made to the principal investigator, research staff, or other contact people noted on the consent form or other study materials. Complaints may also be made directly to the IRB.
2. Documents submitted to the IRB regarding an unanticipated problem
 - a. The investigator is required to report any adverse event by submitting a written report using the *Report of Adverse Event* form within 10 business days of becoming aware of the event.

- b. The investigator is required to report any protocol deviation by submitting a written report using the *Report of Protocol Deviation* form within 10 business days of becoming aware of the deviation.
- c. The investigator is required to report any complaints made by participants or others regarding conduct of the study by submitting a written report using the *Report of Study Related Complaint* form within 10 business days. When someone other than the investigator reports a complaint to the IRB, there is no specific format required.

If a complaint is prompted by an event that is assessed as a reportable adverse event or a reportable protocol deviation, the following reporting procedures should be followed:

- i. Guidelines related to reporting either an adverse event or a protocol deviation should be followed
- ii. The applicable reporting form should be used
- iii. The report should note that a complaint has been made in relation to the event
- iv. At the time of the continuing review the event should be reported as both a complaint and an adverse event or protocol deviation as applicable.

3. Type of review and the range of possible actions the IRB may take

a. Type of review

The chair or designee will review all reports of unanticipated problems and serious or continuing noncompliance and notify the other members of the IRB as appropriate to the severity of the risk to human subjects or others. The chair may report and schedule discussion of the problem at the next regularly scheduled IRB meeting or may convene a more immediate meeting to review the problem in terms of the risks to participants.

In circumstances where the IRB chair becomes aware of possible non-compliance, the chair will evaluate the information at hand and make a preliminary determination as to how the information or event should be categorized. The final designation of an event as either serious or continuing non-compliance, as well as the action required, will be determined at a convened IRB meeting.

b. Range of possible actions the IRB may take

Depending upon the severity or nature of the problem, the IRB may decide to reconsider approval of the research project; require modifications to the procedures and/or the informed consent form; and/or revise the schedule of continuing review.

C. Reviewing information about serious or continuing noncompliance with the regulations or IRB requirements or determinations

1. What might qualify as serious or continuing noncompliance

a. Noncompliance is defined as failure to comply with federal regulations; the policies or procedures of the IRB; or ethical principles governing human research. Examples of noncompliance include:

- i. conducting human participant research without IRB approval
- ii. disregarding or otherwise violating IRB-approved informed consent procedures
- iii. deviating from the protocol approved by the IRB
- iv. modifying an approved protocol without IRB consent
- v. failing to report or tardy reporting unanticipated problems
- vi. failing to train research team members in the proper procedures
- vii. failing to follow recommendations by the IRB to ensure the safety of research participants

b. Serious noncompliance is defined as noncompliance which, in the judgment of the convened IRB, significantly increases risk to participants. Examples of serious noncompliance include:

- i. bringing harm to research subjects
- ii. exposing research subjects to a significant risk of substantive harm
- iii. compromising the privacy and confidentiality of research participants
- iv. causing damage to scientific integrity of the research data that has been collected
- v. engaging in willful or knowing noncompliance
- vi. impacting ethical principles adversely

The IRB does not have to find that harm has occurred, or was likely to occur, to make a determination of serious noncompliance.

Multiple instances of noncompliance that are deemed not-serious individually may constitute serious noncompliance when considered collectively.

c. Continuing Noncompliance is defined as a pattern of non-compliance that indicates a lack of understanding or disregard for the regulations or DMHAS policy to protect the rights and welfare of subjects and others, compromises the scientific integrity of a study such that important conclusions can no longer be reached, suggests a likelihood that non-compliance will continue without intervention, or involves frequent instances of minor non-compliance.

OHRP has advised that it considers noncompliance to be continuing if it persists after the investigator knew or should have known about it. In such cases, the DMHAS IRB holds a presumption of continuing noncompliance, placing the burden on the investigator to present compelling, mitigating circumstances. The period in which the continuing noncompliance occurred could be days or weeks (depending on the seriousness of the matter), and the IRB does not need to call an issue noncompliance before being able to call it continuing noncompliance.

2. Documents submitted to the IRB regarding serious or continuing noncompliance

Serious or continuous non-compliance must be reported in writing within 5 business days. The documentation must identify the study name, investigator, date(s) of non-compliance, and a full description of the non-compliant activity.

The IRB chair may also find serious or continuing non-compliance in an IRB audit or ongoing review and will document it as part of the review.

3. Type of review and the range of possible actions the IRB may take

When such incidents occur in relation to studies funded by HHS or funded by a non-HHS departments or agency that has adopted the Final rule, or falls under the jurisdiction of the FDA, the IRB chair will notify OHRP and/or the FDA. The timeframe for reporting the incident will be determined by the chair, who may confer with the IRB regarding the time frame. In general, the time frame for reporting will be based upon the seriousness of the incident, and could range from a matter of days to a matter of weeks. It may be appropriate to send an initial report, and indicate that a follow-up or final report will follow.

The IRB may consider mitigating factors, such as corrective action, that play a role in the determination of whether the event increased risk, decreased potential benefits, or negatively affected the integrity of DMHAS human research protection policy, but if despite these factors, the event's occurrence meets the definition of serious noncompliance, and then the event should be categorized as such.

D. Suspending or terminating approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects

1. Circumstances in which suspending or terminating IRB approval might be appropriate

Suspension or termination of approval may occur in connection with a Continuing Review, but may occur at any time that the IRB deems such action is appropriate

and necessary. Suspension or termination of approval will generally be based upon the concern or conclusion that the research is not being conducted in accordance with the IRB's requirements, and/or that the risk/benefit ratio is no longer acceptable. Related factors that may contribute to suspension or termination are the occurrence of complaints or injuries related to the research, other adverse incidents, or other factors as deemed relevant by the IRB.

2. Informing subjects about the suspension or termination

If a suspension or termination of approval occurs while there are still active participants, the IRB will require that the investigator submit a letter for IRB approval to inform subjects about the suspension or termination

3. Orderly termination of the study, or transfer of the study or study subjects, if applicable

If a suspension or termination of approval occurs while there are still active participants, the IRB will require that the investigator submit a plan for IRB approval for discontinuing any intervention and where appropriate, to refer participants to alternate services.

4. Communicating the reason(s) for the IRB's decision to suspend or terminate approval of the research

In the event of suspension or termination of approval the IRB chair will provide written notice to the investigator including the basis for the action. The chair will also notify the DMHAS IRB Signatory Official, Research Director and the site(s) where the research is being conducted. The chair will also notify the appropriate agency when the research is federally funded, as well as OHRP and the FDA as appropriate and outlined above under XX.

XI. APPLICABILITY OF FEDERALWIDE ASSURANCE

The terms of DMHAS' Federalwide Assurance (FWA) apply whenever DMHAS becomes engaged in human subjects research conducted or supported by any federal department or agency that has adopted the Final Rule, unless the research is otherwise exempt from the requirements of the Final Rule, or a federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance. As such, DMHAS and the IRB designated under its assurance will comply with the Federal Policy for the Protection of Human Subjects (45 CFR 46 and subparts B, C, and D) when engaged in federally conducted or funded research.

The terms of DMHAS ' FWA have not been extended to non-federally conducted or supported research with humans; and DMHAS has not elected to assure application of 45 CFR 46 and subparts B,C and D to non-federally conducted or funded research with humans.

However, when reviewing non-federally funded research, the DMHAS IRB will generally apply the regulations and DMHAS IRB standards in the same manner as with federally funded research. But review and subsequent IRB actions in such cases is subject to flexibility as deemed appropriate by the IRB.

XII. AUTHORIZATION AGREEMENTS WITH NON-DMHAS INSTITUTIONS

In certain circumstances the DMHAS IRB may agree to be designated as the IRB of record for another institution (referred to hereafter as Institution B). When this occurs the DMHAS IRB assumes responsibility for the review and continuing oversight of research on behalf of Institution B. This type of agreement is documented by way of an executed Authorization Agreement signed by the signatory officials designated in DMHAS' and Institution B's Federalwide Assurance. The agreement may be limited to a specific research project(s) or may be broader in scope. The Authorization Agreement will specify the scope of the agreement. The DMHAS IRB will report its findings and actions to Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the DMHAS IRB's determinations and with the Terms of its OHRP-approved FWA. The Authorization agreement should be kept on file by both parties and will be provided to OHRP upon request.

Conversely, in certain circumstances, the DMHAS IRB may agree to accept the findings of another institution's IRB. In this case, DMHAS will be designated as Institution B; the other institution's IRB (referred to hereafter as Institution A) becomes the IRB of record and assumes responsibility for the review and continuing oversight of the research on behalf of DMHAS. The same responsibilities and reporting requirements as outlined above will hold. Also as above, this agreement will be documented by way of an Authorization Agreement; Institution A will report its findings to DMHAS and DMHAS will ensure compliance with Institution A's findings.

XIII. EXTENSION OF DMHAS' FEDERALWIDE ASSURANCE TO A NON-ASSURED INSTITUTION

Department of Health & Human Services (HHS) regulations require that each institution engaged in HHS-conducted or -supported human subjects research provide written assurance, satisfactory to HHS, that it will comply with the requirements of the HHS regulations for the protection of human subjects, unless the research is exempt under 45 CFR 46.101(b). HHS regulations at 45 CFR 46.103(b) require that each institution engaged in HHS-conducted or -supported human subjects research certify to the HHS funding agency that the research has been approved by an IRB designated in the assurance.

In certain circumstances DMHAS may agree to extend the terms of its Federalwide Assurance to another non-assured institution involved in collaborative research with DMHAS. Generally DMHAS will agree to extend its Federalwide Assurance to another institution if the institution does not have its own Federalwide Assurance owing to the fact that the institution does not routinely conduct human subjects research. DMHAS may also extend its Federalwide Assurance to independent investigators collaborating with DMHAS if the independent investigator is not

affiliated with an assured institution. Both institutional and independent investigators must meet the conditions for extending a Federalwide Assurance as outlined by OHRP.

The extension of DMHAS's Federalwide Assurance is documented by way of an executed Individual Investigator Agreement signed by the non-assured institution designee or independent investigator and the signatory official designated in DMHAS' Federalwide Assurance. The agreement may be limited to specific research projects or may be broader in scope. The Individual Investigator Agreement will specify the scope of the agreement.

When DMHAS extends its Federalwide Assurance to another institution or individual the DMHAS IRB becomes the designated IRB of record for the non-assured institution or independent investigator with respect to the research project(s) covered by the Individual Investigator Agreement.

XIV. IRB MEMBERSHIP AND RESPONSIBILITIES

A. Number of IRB members

The IRB will consist of at least five members.

B. Ensuring diversity in IRB membership

Members must be sufficiently diverse to enable adequate review of the range of research that is commonly reviewed by the IRB (e.g., representation of genders, multiple professions, scientific and nonscientific members, nonaffiliated members).

C. Selecting and appointing the IRB chairperson, the members, and alternate members

The Commissioner, as the Signatory Official for the DMHAS' FWA, will appoint the IRB chair and IRB members.

As deemed necessary, a specific individual may be designated as an alternate for a specific IRB member. The alternate should, in general, have the same professional background, experience and expertise as the standing member. The Signatory Official also appoints alternate members and the alternate's term is consistent with the standing member's term. It is the standing members' responsibility to ensure that the alternate has adequate information and preparation related to specific issues and studies to enable the alternate to make an informed vote. Alternate members will receive all of the same IRB and study materials that standing members receive. Alternate members may attend any IRB meeting but may vote only in the absence of the standing member.

1. Length of term or service

Appointment will be for a two-year term. There is no limit on the number of terms the chair or a member may serve. New members may review and vote on

research proposals and other matters only after completion of new member orientation and human subjects protection education.

2. General description of duties

a. Responsibilities of IRB chair

- i. Compliance with regulations governing IRB activities
- ii. Maintain DMHAS FWA and IRB registration via the HHS registration system
- iii. Conduct expedited reviews, in accordance with regulations
- iv. Manage IRB meetings: Prepare and distribute schedules, agendas, study materials, and minutes to IRB members
- v. Prepare Report of IRB Activity for months where the IRB does not convene
- vi. Maintain IRB records as outlined in this policy
- vii. Maintain a current list of all studies under the review of the IRB including actions taken and corresponding dates
- viii. Send notices of IRB action to investigators and others as appropriate
- ix. Track study approvals and scheduling continuing review to prevent lapses in IRB approval, including procedures to follow if IRB approval lapses
- x. Handle subject complaints, problems, concerns and questions about rights as a research subject
- xi. Orient and conduct ongoing education of IRB members
- xii. Represent the DMHAS IRB in communications with investigators, DMHAS staff, and others as required
- xiii. Provide access to information about IRB requirements and written procedures

b. Responsibilities of IRB Members

- i. Regular attendance at IRB meetings
- ii. Review research proposals prior to the meetings in sufficient detail to enable informed voting
- iii. Vote on research proposals and other actions before the convened IRB
- iv. Bring issues to the attention of the convened IRB as appropriate; and
- v. Complete required educational activities

3. Attendance requirements

Members are expected to attend and participate in 80% of scheduled meetings of the convened IRB. If any member anticipates an extended leave of absence (more than two meetings), due to unavoidable factors, the member may request to be categorized as "on temporary leave" from the IRB. During the leave the member will not be considered when determining whether or not there is a quorum.

Should the leave extend beyond six months the member will be withdrawn from the IRB with the option of rejoining at a later date.

4. Qualifications of the IRB chairperson, members and any alternate members

a. IRB chair

The chair must have extensive knowledge and experience in the area of human subjects protection regulations. The chair must have sufficient knowledge of research to review all studies presented to the IRB and communicate with other reviewers as needed so that important IRB issues or concerns are resolved or identified prior to the convened IRB meeting, and be able to effectively administer IRB records and meetings, and direct the proceedings and discussion of convened IRB meetings.

b. IRB Members

i. Scientific IRB Member

The IRB Scientific Member must hold a scientific degree (e.g., M.D., D.O., Ph.D., Pharm.D. or Bachelor of Science in Nursing). Scientific members must have professional training and experience in an occupation that would incline them to view scientific activities from the standpoint of someone within a behavior or biomedical research discipline.

ii. Non-Scientific IRB Member

The IRB Non-Scientific Member must have experience with complex information processing and interpersonal communication. In addition, the non-scientific member must be comfortable with the electronic environment and able to navigate in email and the internet. Examples of non-scientific or non-medical occupations may include, but not limited to, social workers, lawyers, clergy, ethicists, teachers, engineers, accountants, musicians, or business majors.

iii. Non-Affiliated (Community) IRB Member

The Non-Affiliated IRB Member is experienced with complex information processing, interpersonal communication, and is sensitive to unique community populations and cultures. In addition, the non-affiliated member must be comfortable with the electronic environment, able to navigate in email, and have access to high-speed internet.

iv. Prisoner representative

A prisoner representative must have appropriate background, relevant experience and a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner.

5. The criteria used to categorize members and alternate members as scientist, nonscientist, and nonaffiliated

- a. Scientific members are expected to contribute to the evaluation of a research project on its scientific merits and standards of practice. These members are able to advise the IRB if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects.
- b. Nonscientific Members: Nonscientific members are expected to provide input on matters germane to their individual knowledge, expertise and experience, professional and otherwise. Nonscientific members advise the IRB if additional expertise in a nonscientific area is required to assess if research project adequately protects the rights and welfare of subjects.
- c. Non-Affiliated (Community) Members: Non-affiliated members are expected to provide input regarding their individual knowledge about the local community and be willing to discuss issues and research from that perspective. A non-affiliated member is also a scientific or nonscientific member and would be expected to provide input on areas germane to his/her knowledge, expertise and experience, professional and otherwise.

XV. IRB Records

A. Records that are retained

1. Research Proposal Files
 - a. Original IRB Application/research proposal
 - b. Reviewer checklist
 - c. Approved IRB Application/research protocol, consent form and other material related to approved study with approval and approval expiration dates affixed by the IRB chair
 - d. Application for continued approval
 - e. Notice of IRB action(s)
 - f. All correspondence related to study
 - g. Statements of significant new findings provided to participants, if any
 - h. Reports of adverse events, protocol deviations and participant complaints, if any
 - i. Minutes of convened IRB meetings where the study was discussed

j. Other documents as deemed relevant.

2. List of IRB members

- a. In addition to a list of members of the DMHAS IRB, the following information will be kept for each member in separate files
 - i. Name
 - ii. Earned degree
 - iii. Representative capacity
 - iv. Indication of experience sufficient to describe chief anticipated contribution
 - v. Employment status with or relationship to DMHAS
 - vi. IRB member resumes and appointment letters
 - vii. IRB member training records

3. Minutes of convened IRB meetings

Minutes will provide a summary of what occurred during a convened IRB meeting and provide information to persons not present at the meeting (e.g., investigators, institutional officials, regulators, IRB members who could not attend) about what the IRB reviewed and the actions taken by the IRB. Minutes will contain the following information:

- a. Meeting date, time, and location
- b. Attendance and whether a quorum was achieved; loss of quorum
- c. Research proposals reviewed
- d. Type of review
- e. Summary of discussions of issues and their resolution
- f. Where HHS regulations require specific findings on the part of the IRB, documentation of the findings and, where necessary, protocol-specific information related to each finding
- g. IRB action including total number in attendance and members voting for, against and abstaining
- h. Interval of approval
- i. Basis for requiring changes and for disapproval
- j. Other activity of the IRB

Minutes are confidential and are available only to IRB members, the Signatory Official of the DMHAS Federalwide Assurance, and the person to whom the IRB chair directly reports, unless the latter two are involved in the research under question, in which case minutes would not be available to these parties.

4. Monthly Report of IRB Activities

B. Where records are stored

All records are stored electronically on the chair's T drive.

C. Record Retention

Records related to the conduct and documentation of IRB activities will be maintained for at least 3 years after completion of the research. Records are accessible for inspection.

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