Oakwood University Privacy and Confidentiality Policy

A guiding principle of research involving human volunteers is that a participant's privacy must be respected and confidentiality of person-identifiable data must be preserved.

The OU IRB will determine whether there is an appropriate plan to protect the confidentiality of research data that may include coding, removal of identifying information, limiting access to data, use of Certificates of Confidentiality or other effective methods. The OU IRB will also determine whether methods used to identify and recruit potential participants protect subject privacy and confidentiality and whether the informed consent form adequately discloses the risks to privacy and confidentiality. Physical safeguards for research data will also be reviewed by the IRB, such as maintenance of records in locked files, separation of person-identifiable demographics data from study data referenced only to a unique study ID, etc.

Access to research data should be based on a "need to know" and "minimum necessary" standard. Investigators should use and communicate person-identifiable information about research participants only when it is essential to the scientific goals of a research study. Regarding access to personal information, the IRB will consider the methods for reducing potential privacy concerns when the private information prior to approval, when the personal information: 1) is being accessed without the participant's knowledge and explicit permission, e.g., under a waiver of consent or HIPAA authorization, before consent, during recruitment and screening, under an exempt protocol; 2) concerns sensitive information; 3) involves covert observation of non-public activity.

As a general policy, the criteria used by the IRB for judging the safeguards for participant confidentiality will be those of the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Although HIPAA addresses only a specifically defined set of information called Protected Health Information (PHI) derived from healthcare service events, its principles represent a best practice for all person-identifiable research data.

In the informed consent procedure, subjects are often given assurances that the confidentiality of records identifying the subjects will be maintained. Loss of confidentiality may occur however when a court orders that research files or information be submitted as evidence in a legal matter. The court decides who has access to the files and what information may be required.

Privacy Rule/HIPPA

The HIPAA Privacy Rule permits researchers to access, use or disclose protected health information (PHI) for research purposes when a researcher receives formal written authorization from a subject, which permits such use in accordance with the requirements of the Rule at 45 CFR 164.508. (Attachment I for Authorization to use PHI form) In certain limited situations, researchers may also access, use or disclose PHI for research without obtaining a written approval from a subject by obtaining a formal waiver of individual authorization from an IRB

Only projects that have already been determined by Oakwood University IRB to meet the regulatory criteria of exempt research will be considered. A decision will be made to approve or disapprove (i.e., authorization required) the request.

ELEMENTS OF A CONSENT / AUTHORIZATION USING PERSONAL HEALTH INFORMATION (PHI)

A. The authorization section of the form must set out the specific information stipulated in the Privacy rule:

    1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

    2. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

    3. The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

    4. A description of each purpose of the requested use or disclosure. The statement, "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

    5. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization. The statement, "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

    6. Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

B. Required statements. In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

    1. The individual's right to revoke the authorization in writing, and either:

        a. The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

        b. To the extent that the information in (A) of this section is included in the notice required by § 164.520, a reference to the covered entity's notice.

    2. The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

        a. The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations applies; or

        b. The consequences to the individual of a refusal to sign the authorization when the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

    3. The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.

C. Plain language requirement. As with the Consent element of the form, the authorization must be written in plain language.

D. Copy to the individual. If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

WAIVER OF AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION (PHI)

To use or disclose PHI without authorization by the research participant, Oakwood College must obtain one of the following:

A. Documentation that an amendment or waiver of the research participants' authorizations, for use/disclosure of PHI has been approved by the IRB. This provision of the rule might be used for example, to conduct records research, when researchers are unable to use de-identified information; or

B. Where researchers represent:

1. That the research is only for purposes of preparing a research protocol or similar uses preparatory to research.

2. That he or she will not remove any PHI from the covered entity; and

3. That PHI is necessary for the research purpose; or

C. To disclose PHI of decedents, where the researcher represents that the use or disclosure of PHI is:

1. Solely for research on the PHI of decedents;

2. Necessary for the research; and

3. Documentation of the death of the individuals about whom PHI is sought and provided.

In addition, the researcher is required to provide:

A. Documentation indicating that an amendment to, or waiver, in whole or in part, of the individual authorization required by 45 C.F.R §164.508 for use or disclosure of protected health information, has been approved by the Institutional Review Board (IRB).

B. Documentation of approval of an amendment or waiver must include the following information:

1. A statement identifying the IRB and the date on which the amendment or waiver of authorization was approved;

2. A brief description of the protected health information for which use or access has been determined to be necessary by the IRB;

3. A statement that the amendment or waiver of authorization has been reviewed and approved under either normal or expedited review procedures following the requirements of the Common Rule, including the normal review procedures.

4. A statement that the amendment or waiver of authorization has been reviewed and approved, under either normal or expedited review procedures, by the IRB which reviews proposed research at convened meetings;

5. A statement that the IRB has determined that the authorization may be altered or waived, in whole or in part, indicating:

a. The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

i. an adequate plan to protect the identifiers from improper use and disclosure;

ii. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and

iii. adequate written assurances that the protected health information 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 for which the use or disclosure of protected health information would be permitted by the Privacy rule.

b. The research could not practicably be conducted without access to, and use of, the protected health information.

C. Documentation of the amendment or waiver of authorization must be signed by the chair or other member, as designated by the chair of the IRB, as applicable.

D. Prior to a review preparatory to research, the IRB will obtain from the researcher representations that:

1. Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

2. No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

3. The protected health information for which use or access is sought is necessary for the research purposes.

E. Prior to research using information relating to decedent(s), the IRB will obtain from the researcher:

1. Representations that the use or disclosure sought is solely for research on the protected health information of decedents;

2. Documentation, at the request of the IRB, of the death of such individuals; and

3. Representation that the protected health information, for which use or disclosure is sought, is necessary for the research purposes.

F. Personnel receiving a request from an individual or entity for use or disclosure of protected health information will determine whether the requesting individual is a person with whom the IRB has a knowing relationship.

G. Personnel will follow appropriate policies and procedures for verifying the identity and authority of individuals requesting protected health information.

H. Once it is determined that use or disclosure is appropriate, personnel with appropriate access clearance will access the protected health information using proper access and authorization procedures.

I. The requested protected health information will be delivered to the requesting individual in a secure and confidential manner, such that the information cannot be accessed by employees or other persons who do not have appropriate access clearance to that information.

J. Personnel will appropriately document the request and delivery of the protected health information.

K. In the event that the identity and legal authority of an individual or entity requesting protected health information cannot be verified, Staff will refrain from disclosing the requested information and report the case to the Oakwood University Institutional Review Board in a timely manner.

L. Knowledge of a violation or potential violation of this policy must be reported directly to the Oakwood University Institutional Review Board

Overview of the Privacy Rule and the IRB Role

The Privacy Rule, at 45 CFR parts 160 and 164, establishes a category of health information, defined as protected health information (PHI), which a covered entity may only use or disclose to others in certain circumstances and under certain conditions. In general, the Privacy Rule requires an individual to provide signed permission, known as an Authorization under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual's PHI for research purposes. Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's Authorization. One way a covered entity can use or disclose PHI for research without an Authorization is by obtaining proper documentation of a waiver of the Authorization requirement by an Institutional Review Board (IRB) or a new type of review body, a Privacy Board.

An IRB's authority to approve a waiver or an alteration of the Privacy Rule's Authorization requirement is new and in addition to, not in lieu of, the traditional IRB authorities to protect research participants from risks under 45 CFR part 46 (Department of Health and Human Services [HHS] Regulations for the Protection of Human Subjects) and 21 CFR parts 50 and 56 (Food and Drug Administration [FDA] Regulations on Protection of Human Subjects). Other Federal and State laws and regulations may impose other or additional restrictions and limitations on the use of health information for research that may not be waived or altered by an IRB or Privacy Board under the authority granted to it by the Privacy Rule.

Introduction to the Privacy Rule

In response to a congressional mandate in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HHS issued regulations entitled *Standards for Privacy of Individually Identifiable Health Information*. For most covered entities, compliance with these regulations, known as the Privacy Rule, was required by April 14, 2003.

The Privacy Rule is a response to public concern over potential abuses of the privacy of health information. The Privacy Rule establishes a category of health information, PHI, which may only be used or disclosed to others in certain circumstances or under certain conditions. PHI is a subset of what is termed *individually identifiable health information*. With certain exceptions, individually identifiable health information becomes PHI when it is created or received by a covered entity. Covered entities are health plans, health care clearinghouses, and health care providers that transmit health information electronically in connection with certain defined HIPAA transactions, such as claims or eligibility inquiries. Researchers are not themselves covered entities, unless they also provide health care and engage in any of the covered electronic transactions. If, however, researchers are employees or other workforce members of a covered entity (e.g., a hospital or health insurer), they may have to comply with that entity's new HIPAA privacy policies and procedures. A researcher who is not himself or herself a covered entity or is not a workforce member of a covered entity may be indirectly affected by the Privacy Rule, if a covered entity supplies the research data.

IRB Role under the Privacy Rule

Beginning on April 14, 2003, the Privacy Rule's compliance date for most covered entities, IRBs gained authority to consider, and act upon, requests for a partial or complete waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of PHI for research. Although HHS and FDA Protection of Human Subjects Regulations include protections to help ensure the privacy of subjects and the confidentiality of information, the Privacy Rule supplements these protections by requiring covered

entities to implement specific measures to safeguard the privacy of PHI. If certain conditions are met, an IRB may grant a waiver or an alteration of the Authorization requirement for research uses or disclosures of PHI.

Provisions concerning requests to an IRB for a waiver or an alteration of the Authorization requirement are in section 164.512(i) of the Privacy Rule. It is likely that IRBs will be primarily involved in acting on requests for waiver or alteration of the Authorization requirement in connection with research activities that the particular IRB oversees. The Privacy Rule does not impose any requirements for the location or sponsorship of an IRB convened for the purposes of acting on a request for approval of a waiver or an alteration of the Authorization requirement. Thus, an IRB approval for a waiver or an alteration of Authorization may be issued by an IRB that is unrelated to the institution conducting or sponsoring the specific research project, unrelated to the covered entity that creates or maintains the PHI to be used or disclosed for research, or different from the IRB with responsibility for monitoring the underlying research project. As a result, a waiver or an alteration of the Privacy Rule's Authorization requirements could be obtained from a single IRB in connection with a multisite research activity or where the PHI necessary for the research will be used or disclosed by more than one covered entity.

Under the Privacy Rule, an Authorization may be combined with the informed consent document for research. If the informed consent document is combined with an Authorization meeting the Privacy Rule's requirements, 45 CFR part 46 and/or 21 CFR parts 50 and 56 would require IRB review of the combined document.

An IRB's role under the Privacy Rule, however, is limited to acting on requests for a waiver or an alteration of the Privacy Rule's Authorization requirement. IRBs are, thus, not required to review and approve Authorizations under the Privacy Rule. Likewise, IRBs are not required to approve stand-alone Authorizations (i.e., Authorizations that are not incorporated into the informed consent document) under the HHS Protection of Human Subjects Regulations at 45 CFR part 46 or the FDA regulations at 21 CFR parts 50 and 56. However, FDA regulations at 21 CFR parts 50 and 56 would require such review if required by the IRB's written procedures. In the exercise of ongoing enforcement discretion, however, with respect to the requirements of 21 CFR 56.108(a), to the extent that an IRB's written procedures require the review and/or approval of stand-alone Authorizations, FDA will not take enforcement action against an IRB for failing to review them even when the IRB's written procedures otherwise would require such review and/or approval. Moreover, the Privacy Rule does not require IRBs to review uses and disclosures of an individual's PHI that are made with an individual's Authorization.

Waivers or Alterations of the Authorization Requirements

For some types of research, it is impracticable for researchers to obtain written Authorization from research participants. To address this type of situation, the Privacy Rule contains criteria for waiver or alteration of the Authorization requirement by an IRB or a Privacy Board. Under the Privacy Rule, either board may waive or alter, in whole or in part, the Privacy Rule's Authorization requirements for the use and disclosure of PHI in connection with a particular research project.

A waiver in whole occurs when the IRB determines that no Authorization will be required for a covered entity to use or disclose PHI for a particular research project because certain criteria set forth in the Privacy Rule have been met (see section 164.512(i) of the Privacy Rule). For example, if a study involved the use of PHI pertaining to numerous individuals where contact information is unknown, and it would be

impracticable to conduct the research if Authorization were required, an IRB could waive all of the Authorization requirements for research participants if the IRB determined that all of the Privacy Rule waiver criteria had been satisfied. If the IRB approves such a waiver, the receipt of the requisite documentation of the approval permits a covered entity to use or disclose PHI in connection with a particular research project without Authorization. A partial waiver of the Authorization requirements of the Privacy Rule might be requested, for instance, to allow a researcher to obtain PHI as necessary to recruit potential research subjects. For example, even if an IRB does not waive the Authorization requirement for the entire research study, an IRB may partially waive the Authorization requirement to permit a covered entity to disclose PHI to a researcher for the purposes of contacting and recruiting individuals into the study.

An IRB may also approve a request that removes some, but not all, required elements of an Authorization (an alteration). For example, an IRB may alter the Authorization to remove the element that describes each purpose of the requested use or disclosure where, for example, the identification of the specific research study would affect the results of the study. Before a covered entity could use or disclose PHI pursuant to the altered Authorization, however, it must receive documentation that an IRB determined that all of the Privacy Rule waiver criteria at section 164.512(i)(2)(ii) had been satisfied. Any subsequent use or disclosure of PHI by a covered entity for a different research study would require an additional Authorization, except as permitted without Authorization under section 164.512(i) (e.g., with a waiver of Authorization) or 164.514(e) (i.e., as a limited data set with a data use agreement).

The Privacy Rule establishes the criteria to be evaluated by an IRB in approving an Authorization waiver or alteration. Furthermore, the criteria for an IRB waiver or alteration of the Authorization are consistent with the criteria for IRB waiver of the informed consent requirements contained in the HHS Protection of Human Subjects Regulations. For a covered entity to use or disclose PHI under a waiver or an alteration of the Authorization requirement, it must receive documentation of, among other things, the IRB or Privacy Board's determination that the following criteria have been met:

- The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of (1) an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
- The research could not practicably be conducted without the requested waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.

IRB Review Proceedings

IRB Composition

The Privacy Rule does not change the composition of an IRB. Under the HHS and FDA Protection of Human Subjects Regulations each IRB must have at least five members with varying backgrounds to

promote complete and adequate review of research activities conducted by the institution. An IRB must be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB must also be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. No IRB may consist entirely of members of one profession. In addition, at least one member must not be affiliated with the institution (or part of the immediate family of a person affiliated with the institution). Furthermore, no IRB may have a member participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information at the request of the IRB. Each IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The Privacy Rule permits a covered entity to accept documentation of waiver or alteration approval from any qualified IRB or Privacy Board—not only the IRB overseeing the institution's research.

IRB Procedural Requirements

When acting upon a request to waive or alter the Authorization requirement, an IRB must follow the procedural requirements of the HHS Protection of Human Subjects Regulations and/or, if applicable, FDA regulations, including using either the normal review procedures (review by the convened IRB) or the expedited review procedures. The FDA Protection of Human Subjects Regulations also require the IRB to follow its established written procedures whether a request for a waiver or an alteration of the Authorization requirement is considered by a convened IRB or by an IRB under the expedited review procedures.

Review by the Convened IRB

When a request for a waiver or an alteration of the Authorization requirement is considered by the convened IRB, a majority of the IRB members must be present at the meeting, including at least one member whose primary concerns are in nonscientific areas. In order for an approval of a waiver or an alteration of the Privacy Rule's Authorization requirement to be effective, it must be approved by a majority of the IRB members present at the convened meeting. If a member of the IRB has a conflicting interest with respect to the PHI use and disclosure for which a waiver or an alteration approval is being sought, that member may not participate in the review.

Expedited Review

HHS and FDA have established categories of research that may be reviewed by an IRB through an expedited review procedure. Expedited review of a request for a waiver or an alteration of the Authorization requirement is permitted where the research activity is on the HHS or FDA list of approved categories[i] and involves no more than minimal risks. In addition, 45 CFR 46.110 and 21 CFR 56.110 permit an IRB to use an expedited review procedure to review minor changes in previously approved research. A modification to a previously approved research protocol, which only involves the addition of an Authorization for the use or disclosure of PHI to the IRB-approved informed consent, may be reviewed by the IRB through an expedited review procedure, since this type of modification may be considered to be no more than a minor change to research. If expedited review procedures are appropriate for acting on the request, the review may be carried out by the IRB chair or by one or more experienced reviewers designated by the chair from among the IRB members. A member with a conflicting interest may not participate in an expedited review. If an IRB uses expedited review procedures, it must adopt

methods for keeping all its members advised of requests for waivers or alterations of the Authorization requirement as well as those requests that have been granted under an expedited review procedure. If the head of the Federal department or agency (or his/her designee) regulating the research has restricted, suspended, terminated, or chosen not to authorize an institution or IRB to use expedited review procedures, the IRB cannot grant waivers or alterations of the Authorization requirement on an expedited basis.

Documentation of Authorization Waiver or Alteration Determinations

Before a covered entity may use or disclose PHI for research based on a waiver or an alteration of Authorization by an IRB, a covered entity must receive documentation showing the following:

- The identity of the approving IRB
- The date on which the waiver or alteration was approved
- A statement that the IRB has determined that all the specified criteria for a waiver or an alteration were met
- A brief description of the PHI for which use or access has been determined by the IRB to be necessary in connection with the specific research activity
- A statement that the waiver or alteration was reviewed and approved under either normal or expedited review procedures
- The required signature of the IRB chair or the chair's designee

As noted, the IRB's documentation of its approval must describe the PHI for which use or access has been determined to be necessary for the research. This would include stating, for example, that the waiver was limited to only certain information in a patient's medical record, instead of the entire record. If a covered entity uses or discloses PHI based on an IRB approval of a waiver or an alteration of the Authorization requirement, the covered entity must retain the IRB's documentation on which it relied for at least 6 years from the date the waiver or alteration was obtained, or the date when it was last in effect, whichever is later.

Other provisions of applicable Federal law and regulations, as well as the written policies and procedures of a specific IRB, may require the IRB to create and maintain additional documentation of its actions on requests to approve a waiver.

Verification Requirements: Right to Rely

In some circumstances, IRBs and Privacy Boards will coexist. Where these boards coexist, the Privacy Rule requires approval of a waiver or an alteration of Authorization by only one of them. Furthermore, a covered entity may use or disclose PHI based on a waiver or an alteration of Authorization approved by any IRB or Privacy Board, without regard to the location or affiliation of the IRB or Privacy Board. The Privacy Rule permits a covered entity reasonably to rely on an IRB's or a Privacy Board's documentation granting a waiver or alteration of the Authorization requirement so long as the documentation is proper. The documentation on which the covered entity relies must be in writing and meet the signature and other requirements discussed in the Documentation of Authorization Waiver.

A covered entity's ability reasonably to rely on documentation of an Authorization waiver or alteration may be especially important for research projects taking place at multiple sites and/or requiring the use

and disclosure of PHI created or maintained by more than one covered entity (collectively, multisite projects). Often, different IRBs are involved in multisite project reviews. For these situations, HHS has stated (65 *Federal Register* 82692, December 28, 2000) that a covered entity's responsibility is only to "obtain the documentation that *one* IRB or [P]rivacy [B]oard has approved the alteration or waiver of Authorization." (Emphasis added.) Consequently, the Privacy Rule allows a waiver or an alteration of Authorization obtained from a single IRB to be used to obtain PHI in connection with multisite projects. However, HHS also recognizes that "covered entities may elect to require IRB reviews before disclosing [PHI] to requesting researchers" (67 *Federal Register* 53232, August 14, 2002). The Privacy Rule does not require entities to change their practices with respect to how they address potential splits between review boards. However, HHS "strongly encourages researchers to notify IRBs and [P]rivacy [B]oards of any prior IRB or [P]rivacy [B]oard review of a research protocol" (65 *Federal Register* 82692, December 28, 2000).

A covered entity must limit the use or disclosure of PHI for research that is based on documentation of an approved waiver or alteration of Authorization to the minimum necessary to accomplish the intended purpose of the particular research protocol or project (see section 164.502(b) of the Privacy Rule). Documentation supporting an IRB's approval of a waiver or an alteration of Authorization must include a description of the PHI without access to and use of which the IRB has determined the research could not practicably be conducted. If an IRB has granted a waiver or an alteration of Authorization, a covered entity may rely, if such reliance is reasonable under the circumstances, on the IRB's documentation to satisfy itself that the requested PHI use or disclosure is limited to the minimum necessary for the stated research purpose (see section 164.514(d)(3)(iii) of the Privacy Rule). Such reliance is appropriate regardless of whether the documentation of waiver or alteration is obtained from an external IRB or associated with the covered entity relying on the documentation (see 67 *Federal Register* at 53198, August 14, 2002).