

**INSTITUTIONAL REVIEW BOARD:
POLICIES AND PROCEDURES FOR COMPLYING WITH PRIVACY LAWS THAT
AFFECT USE AND DISCLOSURE OF PHI IN RESEARCH**

Notes

1. These policies are written to assist the University Institutional Review Board in complying with the federal Privacy Rule promulgated under HIPAA.
2. These policies are designed to address data issues the Privacy Rule creates for all types of health research: clinical research, survey research, medical records research, and research using biological materials.

**INSTITUTIONAL REVIEW BOARD:
POLICIES AND PROCEDURES FOR COMPLYING WITH PRIVACY LAWS THAT
AFFECT USE AND DISCLOSURE OF DATA FOR RESEARCH**

APPLICABILITY: These policies and procedures govern the operation of the University of Miami Institutional Review Board (“IRB”) in its relationship with the University of Miami and/or Jackson Health System health care facilities (hereinafter each referred to as a “Covered Entity” or “Covered Entities”). They also apply to any other entities and/or protocols for which the University IRB is the IRB of record.

POLICY STATEMENT: Research by investigators affiliated with a Covered Entity, and by third party investigators who may be affiliated with the Covered Entity or a third party sponsor, fills an important function for a Covered Entity and for patients who may now or in future benefit from research insights and therapeutic developments. Where a Covered Entity has provided in its Notice of Privacy Practices that medical records may be used in research, data may be made available in accord with these policies 1 through 6. These policies govern use of data by investigators who are part of the workforce of a Covered Entity, or are clinicians that are members of an Organized Health Care Arrangement with or on staff at the Covered Entity, or those in a business associate with Covered Entity for purposes of providing research review and/or recruitment services. These policies also govern disclosures of data to investigators who are non-clinical personnel affiliated with the Covered Entity, or who are employees or contractors of third party research sponsors.

It is the policy of Institutional Review Board to facilitate compliance with applicable laws and regulations that govern use or disclosure of health information for research by Covered Entity, its affiliated investigators and their third party sponsors. In particular, all research performed using data maintained by or on behalf of, or created about or received from patients of Covered Entity shall be conducted in accord with applicable requirements of federal health privacy standards promulgated by the Department of Health and Human Services (HHS) pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (the “Privacy Rule”), (“the Security Rule”) and analogous state laws and regulations.

APPLICABLE LAW: 45 C.F.R. parts 160, 164; state laws also may apply.

PROCEDURES FOR IMPLEMENTATION: As provided in the policies of Covered Entity, the IRB shall evaluate all research proposals involving the use or disclosure of protected health information maintained by or on behalf of, or created or received from patients of, Covered Entity in accord with applicable standards of the Privacy Rule as described in these Policies and Procedures:

Nature of Research or Protocol Component	Applicable Policy & Procedure
Recruitment of Research Participants and Research Preparation	1.0-1.2

Provision of Research Data to Investigators and Sponsors	2.0-2.4
Exempt Research	3.0-3.1
Research with Biological Materials	4.0
Creation and Use of Institutional Databases and Repositories	5.0-5.2
Transition Rule	6.0

These Policies and Procedures supplement, but do not supplant, other policies and procedures governing IRB review of research protocols at www.hsro.miami.edu (e.g., policies and procedures in compliance with the Common Rule). The IRB shall review research protocols in accord with all applicable institutional policies and procedures.

Definitions

The following definitions are used throughout these Policies and Procedures, except where they appear to be inconsistent with definitions of the same terms codified in the Privacy Rule, or the Common Rule, as applicable. The language of the applicable regulation, as modified from time to time, shall govern in the event of ambiguity or inconsistency.

- **Common Rule**—federal human subject research protections promulgated by the Department of Health and Human Services and codified at 45 C.F.R. part 46 (as amended from time to time) and where applicable, 21 C.F.R. parts 50 and 56.
- **Disclose/disclosure**—the release or transfer of information to, or the provision of access to information by, a person or entity outside of the entity holding the information.
- **Exempt**—research not subject to IRB review for purposes of the Common Rule.
- **Informed consent**—informed consent to participate in research as required by the Common Rule.
- **Interventional**—research in which protected health information is created, obtained, or received by an investigator through physical procedures, manipulation of the research participant or the participant’s environment, or communication or interpersonal contact between the investigator and participant, including prospective observation or analysis of medical care.
- **Limited data set**—protected health information from which direct identifiers have been removed that may be used and disclosed for research purposes pursuant to a data use agreement.

- **Organized Health Care Arrangement** – a clinically integrated care setting, such as a hospital or clinic, where patients receive treatment from more than one provider.
- **Participant (or subject)**—a living individual about whom an investigator conducting research creates, obtains, or receives protected health information.
- **Privacy Rule**—Standards for Privacy of Individually Identifiable Health Information, promulgated by the U.S. Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and codified at part 160 and part 164, subpart E, of Title 45 of the U.S. Code of Federal Regulations (as amended from time to time).
- **Security Rule**- Adopted to implement provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It sets forth specific requirements for the adoption of administrative, physical, and technical safeguards for the protection of electronic protected health information.
- **Protected health information**—information transmitted or maintained in any form (i.e., by electronic means, on paper, or through oral communication) that: (1) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for health care; and (2) identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. As a general matter, protected health information includes any information maintained by or on behalf of, or created about or received from patients of, Covered Entity that includes any of the following identifiers of an individual or an individual’s relatives, household members, or employer(s):
 - names;
 - geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes (three digit zip code may be retained if the resulting geographical area contains more than 20,000 people or, for areas with fewer persons, the three digit zip code is changed to 000);
 - elements of dates (except year) directly related to an individual (e.g., birth date, admission date, discharge date, date of death), as well as any reference to age over 89 and all elements of dates indicative of such age (unless aggregated into a single category of “age 90 or older”);
 - telephone numbers;
 - fax numbers;
 - e-mail addresses;
 - Social Security numbers;
 - medical record numbers;
 - health plan beneficiary numbers;
 - account numbers;
 - certificate and license numbers;

- vehicle identifiers and serial numbers (e.g., license plate numbers, VINs);
- device identifiers and serial numbers;
- Web Universal Resource Locators (“URLs”);
- Internet Protocol (“IP”) address numbers;
- biometric identifiers (e.g., finger and voice prints);
- full-face photographic images and comparable images; and
- any other unique identifying number, characteristic, or code.

[NOTE: “Creating health information” consists of collecting or creating information that will be used in diagnosing a condition of and/or providing treatment to a study participant. Collecting a medical history from the study participant without placing the information in or accessing their medical records is not generally considered “creating health information”. Conducting tests or evaluations not meant to be used for diagnosis or treatment, but rather, for study screening or research information/background purposes is not generally considered “creating health information”.]

- **Research**—a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. “Research” encompasses *any* activity that satisfies this standard, including non-federally funded or supported studies, studies with deceased individuals’ protected health information, and exempt research as defined by the Common Rule.
- **Use**—the sharing, employment, application, examination, or analysis of protected health information within an entity that maintains such information.
- **Workforce**—employees, volunteers, trainees, and other persons whose conduct in the performance of work for Covered Entity is under the direct supervision of Covered Entity. “Workforce” does not include physicians with admitting privileges at Covered Entity.

Appendices

The following appendices are model documents used in these Policies and Procedures:

Appendix	Template
A	Authorization to Use and Disclose Protected Health Information for Research Purposes
B	Documentation of Alteration to or Waiver of Authorization to Use or Disclose Protected Health Information for Research Purposes
C	Data Use Agreement for Disclosure of a Limited Data Set for Research Purposes
D	Investigator Certification for Reviews Preparatory to Research

E	Investigator Certification for Research with Decedents' Information
F	Record of Disclosure of Protected Health Information

SUBJECT: Research Recruitment and Research Preparation

POLICY STATEMENT: The Privacy Rule imposes limitations on the use and disclosure of protected health information for the purpose of identifying and contacting prospective research participants. Similar limitations are imposed when a prospective investigator or third party sponsor seeks to examine existing data of the Covered Entity for purposes of protocol development or evaluation of the Covered Entity's suitability as a research site. The IRB will approve proposals only if they respect these limitations.

APPLICABLE LAW: 45 C.F.R. §§ 164.512(i)(1)(ii), 164.512(i)(2), 164.502(1)(i), 164.528

PROCEDURES FOR IMPLEMENTATION:

- The IRB will follow the procedures set forth in Policy 1.1 with respect to review of protected health information for identification of prospective research participants, evaluation of clinical trial sites, and protocol development.
- The IRB will follow the procedures set forth in Policy 1.2 with respect to use or disclosure of protected health information for the purpose of contacting prospective research participants.

SUBJECT: Research Recruitment—Reviews Preparatory to Research

POLICY STATEMENT: This Policy covers the requirements for identifying patients of Covered Entity who may be prospective study participants, as well as evaluation of the Covered Entity’s patient data for purposes of protocol development or site selection for a clinical trial.

APPLICABLE LAW: 45 C.F.R. §164.512(i)(1)(ii), -.512(i)(2)

PROCEDURES FOR IMPLEMENTATION:

- If a proposal states that a member of Covered Entity’s workforce, a health care provider on-staff, or persons in a business associate with Covered Entity for purposes of providing research review and/or recruitment services will review protected health information maintained by or on behalf of Covered Entity for the purpose of one of the preparatory activities described above, the IRB may approve such review if the workforce member or provider is governed by the following written restrictions:
 - (a) access to the protected health information is solely for the purpose of one or more of the preparatory activities;
 - (b) the requested information is necessary for this purpose; *and*
 - (c) no protected health information will be copied or removed from the premises of Covered Entity during the course of or following the review.

Authorization of the patient is not required.

- If a proposal states that any other person (e.g., an investigator who is not affiliated or in a business associate relationship with Covered Entity) will review protected health information maintained by or on behalf of Covered Entity for the purpose of one of the preparatory activities described above, the IRB may approve such review if the person provides a representation to Covered Entity that meets the following requirements:
 - (a) access to the protected health information is sought solely for the purpose of one or more of the preparatory activities;
 - (b) the requested information is necessary for this purpose; and
 - (c) no protected health information will be copied or removed from the premises of Covered Entity during the course of or following the review.

Authorization of the patient is not required. A template investigator representation is attached as Appendix D.

- As an alternative to obtaining the investigator representation, or where the conditions of the representation cannot be met, the IRB may grant a partial waiver of patient authorization which permits the disclosure of the protected health information to a third party investigator

for the limited purpose of identifying prospective study participants. A decision by the IRB to grant a partial waiver of authorization will be made in accord with Policy 3.2.

- Where an investigator who is not a member of the Covered Entity's OHCA, its workforce, a physician on staff, or a person in a business associate with Covered Entity for purposes of providing research review and/or recruitment services conducts the review, each record reviewed must be annotated with the information necessary to provide an accounting of disclosures. A Template for recording such information is provided in Appendix F. For paper files, a copy may be placed in each record reviewed; analogous procedures may be used to annotate electronic records reviewed.

CROSS REFERENCES:

Policy 3.2 (Review of Non-Exempt Data Research—Waiver of Authorization to Use and Disclose Protected Health Information)

Appendix D (Template for Investigator Representation for Reviews Preparatory to Research-Form E)

Appendix F (Template for Record of Disclosure of Protected Health Information – Attachment 45)

SUBJECT: Research Recruitment—Contacting Prospective Study Participants

POLICY STATEMENT: This Policy covers the requirements for contacting patients of Covered Entity who have been identified as prospective study participants.

APPLICABLE LAW: 45 C.F.R. §§ 164.502(1)(i), -.512(i)(2)

PROCEDURES FOR IMPLEMENTATION:

Without patient authorization or IRB waiver of authorization, the only persons who may use protected health information maintained by or on behalf of Covered Entity to contact a patient about a research opportunity are: (1) members of Covered Entity’s workforce *who have or have had a treatment relationship with the patient* or, if no such relationship exists, provide verification that the health care provider(s) that has or had a direct treatment relationship with the patient(s) has(ve) agreed to allow contact with such patients for the proposed research opportunity; (2) health care providers with current admitting privileges or on staff at Covered Entity who have a treatment relationship with the patient or; (3) those persons in a business associate relationship with Covered Entity for purposes of providing research review and/or recruitment services that provide verification that the health care provider(s) that has or had a direct treatment relationship with the patient(s) has(ve) agreed to allow contact with such patients for the proposed research opportunity.

- The IRB may approve a research protocol that relies on such persons to contact prospective study participants.
- The IRB may grant a partial waiver of patient authorization that permits Covered Entity to disclose patients’ protected health information to another person (e.g., an investigator not affiliated with Covered Entity) for the limited purpose of contacting these patients about a research opportunity. A decision by the IRB to grant a partial waiver of authorization will be made in accord with Policy 3.2.
 - (a) In the case where the IRB grants approval for the Covered Entity staff to refer individuals/patients to the research, the potential subject may contact the researcher, and/or the covered entity itself may contact the potential subject who in turn may sign an authorization to use or disclose (Release) health information that identifies him/her for possible participation in the research study. The appropriate form to use in this case is the JHS and UM Health “Authorization for Release of Individually Identifiable Health Information” which can be found at www.hsro.miami.edu under the HIPAA section.
- If the IRB grants a partial waiver for purposes of allowing a third party investigator to contact prospective participants, the information necessary to make a record of the disclosure must be collected in order to provide each patient with an accounting of disclosures. A Template for recording such information is provided in Appendix F. For paper files, a copy

may be placed in each record reviewed; analogous procedures may be used to annotate electronic records reviewed.

CROSS REFERENCES:

Policy 3.2 (Review of Non-Exempt Data Research—Waiver of Authorization to Use and Disclose Protected Health Information)

Appendix F (Template for Record of Disclosure of Protected Health Information – Attachment 45)

SUBJECT: Provision of Research Data to Investigators and/or Third Party Sponsors

POLICY STATEMENT:

Researchers, including investigators affiliated with a Covered Entity as well as Sponsors and other third party investigators, seek three kinds of access to data for research: (1) data for evaluating a specific or research idea; (2) data that can be re-analyzed to develop new ideas or ways of looking at a problem; and (3) data to meet government requirements regarding the integrity of research.

Except where a limited data set of information is sufficient for the research analysis, the Privacy Rule states that an investigator may not use or obtain data for research purposes unless: (1) each participant (or the participant's legal representative) provides a signed, written authorization to use and disclose the participant's protected health information for the research purpose; *or* (2) the IRB provides documentation of a waiver of authorization to use and disclose participants' protected health information for the research purpose. This requirement is independent of and in addition to any informed consent to participate in research that may be required by the Common Rule or other applicable human subject protection laws and is independent of a waiver of informed consent granted by the IRB.

APPLICABLE LAW: 45 C.F.R. §§ 164.508, 164.512(i)

PROCEDURES FOR IMPLEMENTATION: Investigators who propose to conduct research involving patients of Covered Entity, to engage in prospective collection of data from patients of Covered Entity, or to analyze medical records maintained by Covered Entity regarding its patients, shall indicate to the IRB whether they propose to obtain authorization from each individual. The IRB shall verify that a proposed authorization meets the applicable requirements in accord with Policy 2.1. The IRB shall review requests for waiver or alteration to authorization in accord with Policy 2.2. Where a researcher proposes to analyze medical records maintained by Covered Entity, the IRB shall, wherever possible, encourage use of a data use agreement for a limited data set in accord with Policy 2.3.

SUBJECT: Authorization to Use and Disclose Protected Health Information for Research

POLICY STATEMENT: An investigator who seeks to conduct research, whether interventional research or records research involving patients of Covered Entity, shall obtain signed, written authorization to use and disclose study participants' protected health information for the research purpose, unless the investigator obtains IRB approval for waiver of authorization pursuant to Policy 2.2, or use of the data is limited in accord with Policy 2.3. This requirement is not overridden by a decision by the IRB to waive the requirement of informed consent to participate in the research. This policy and procedure covers the specific content requirements for Privacy Rule authorizations, as well as the requirements for obtaining valid authorization.

APPLICABLE LAW: 45 C.F.R. § 164.508

PROCEDURES FOR IMPLEMENTATION: The IRB will adhere to the following procedures when reviewing research protocols for which authorization is sought.

Authorization Must Be In Writing

Authorization to use and disclose protected health information for research purposes must be in writing unless the IRB waives the writing requirement in accord with Policy 2.2.

Combination with Other Documents

- The authorization *may* be combined with the informed consent to participate in the research (or any other type of written permission for the *same* protocol) to form one document, or it may stand alone as a separate document. If the informed consent (or other written permission) and authorization are combined, it will be important to ensure that each of the elements required by the Privacy Rule is present.
- The research authorization *may not* be combined with any other document, including authorization to use and disclose the protected health information created or obtained during the research for another study or an authorization to place the information in a database or repository for future analysis that is not part of the original protocol (even if informed consent is obtained for both).

Content Requirements

- Unless an element is waived by the IRB in accord with Policy 2.2, an authorization must include, at a minimum:
 - (1) a specific description of the protected health information to be used or disclosed;
 - (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 disclosure;

- (4) a description of the purpose of the requested use or disclosure, *which must be research study-specific*;
 - (5) an expiration date or an expiration event (e.g., “end of the research study”) related to the individual or the purpose of the use or disclosure, *or* a statement that the authorization does not expire;
 - (6) a statement of the individual’s right to revoke the authorization in writing, a description of how to revoke, and the exceptions to the right of revocation (which may include a statement explaining that revocation may result in termination of study participation and does not affect the use and disclosure of existing information as needed to preserve research integrity);
 - (7) a statement describing the ability or inability of Covered Entity and the investigator to condition treatment, payment, enrollment or eligibility for benefits on the authorization (which may include a statement explaining that *research-related* treatment may be conditioned on obtaining the authorization where research involves clinical intervention);
 - (8) a statement that information disclosed pursuant to the authorization may be subject to further disclosure by the recipient and may no longer be protected by the Privacy Rule; and
 - (9) the signature of the individual or personal representative (and, if personal representative, the authority to act for the individual) and date of signature.
- As noted in (4), the authorization must be study or protocol-specific. The IRB will not approve a blanket authorization. This study-specific limitation applies only to protected health information while maintained by the Covered Entity (i.e. health information maintained or included in the patient record, or created during the course of the research); subsequent uses and disclosures of this information for other research purposes require a new authorization or waiver of authorization. By contrast, the study-specific limitation does not restrict further uses of that data by an investigator (or third party sponsor, if any) once the data have been disclosed by or removed from the Covered Entity pursuant to the authorization and made a part of an entirely separate research record; the investigator (and third party sponsor, if any) may obtain permission from research participants through the informed consent process to use this information maintained as part of the separate research record for future, unspecified research activities as permitted by IRB policy.
 - Applicable state health information privacy laws may require additional or more stringent limitations on the use and disclosure of participants’ protected health information or confer on participants additional rights with respect to such uses and disclosures. The IRB will ensure that the contents of the authorization satisfy the requirements of applicable state law (including laws and regulations relating to DNA analysis, HIV status, and treatment in a substance abuse program).
 - The authorization may include additional guarantees of confidentiality of participants’ information by the investigator and other authorized recipients of the information.

- The authorization must be written in “plain language.” The IRB will strive to achieve the same level of understandability and reading comprehension that is required of an informed consent to participate in research. Where appropriate, the IRB will require translations of the authorization to be made available to prospective study participants.
- The research protocol must provide that the research participant will be given a copy of the signed authorization.
- An authorization template (Form B) is attached as Appendix A.

Accounting of Disclosures

Neither Covered Entity nor the investigator is required to record or account for disclosures of protected health information pursuant to an authorization that satisfies the requirements of this Policy 2.1.

CROSS REFERENCES:

Policy 2.2 (Waiver of Authorization to Use and Disclose Protected Health Information)

Policy 2.3 (Data Use Agreement for Limited Data Set – Form C)

Appendix A (Template for Authorization to Use and Disclose Protected Health Information for Research Purposes – Form B)

SUBJECT: Waiver of Authorization to Use and Disclose Protected Health Information

POLICY STATEMENT: An investigator who seeks to conduct research involving patients of Covered Entity or medical records maintained by Covered Entity without obtaining signed, written authorizations that meet the standard set forth in Policy 2.1 must obtain documentation of IRB waiver of the authorization, in whole or in part, in accord with this Policy 2.2, unless use of the data is limited in accord with Policy 2.3. Only if a limited data set as provided in Policy 2.3 is inappropriate for conduct of the research will the IRB consider whether or not to waive authorization. A decision to waive the authorization requirement will be made independently of a decision to waive the Common Rule requirement of informed consent to participate in research. This Policy 2.2 sets forth the process the IRB will follow when reviewing waiver requests, the criteria for approval of waiver, and the IRB's obligations with respect to documentation of waiver.

APPLICABLE LAW: 45 C.F.R. § 164.512(i)(2)

PROCEDURES FOR IMPLEMENTATION: The IRB will review and approve or disapprove requests for waiver of the Privacy Rule authorization requirement, in whole or in part, in accord with the following standards.

Process for Review

The IRB will follow its policies established under the Common Rule for deciding whether review of a request for waiver or alteration of authorization can proceed under either normal or expedited review procedures.

Criteria for Waiver of Authorization

- The IRB may approve a waiver of the authorization requirement, in whole or in part, only if it determines that:
 - (1) the proposed use or disclosure of protected health information involves no more than *minimal risk* to participants' privacy, based on the presence of *at least* the following elements—
 - (a) an adequate plan to protect identifiers from improper use and disclosure;
 - (b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (unless there is a health or research justification for retaining the identifiers, or if retention is otherwise required by law); *and*
 - (c) adequate written assurances that the protected health information will not be reused or disclosed to any third party except as required by law, for oversight of the research, or for other research for which the use or disclosure would be permitted by the Privacy Rule; *and*
 - (2) the proposed research could not practicably be conducted without the waiver or alteration; *and*

- (3) the proposed research could not practicably be conducted without access to and use of the protected health information.
- There is no recognized standard for “minimal risk” to privacy. The IRB will take into account at least the three elements listed in (1), above, when determining whether this standard has been met and may consider other elements as well (e.g., whether safeguards proposed to be used by the investigator are appropriate to the sensitivity of the protected health information). With respect to retention of identifiers, the IRB will consider the need for continued analysis of the data, subsequent government review of the research, and potential for investigation into possible research misconduct when assessing the investigator’s plan for destruction of identifiers.
 - The protected health information made available under a waiver of authorization for research must be the minimum necessary for the research. Although this requirement does not warrant the IRB second guessing which data fields are necessary and appropriate for the research hypothesis, it does bear on a determination of which, if any of the direct or indirect patient identifiers included in the definition of protected health information may be necessary to the research. In determining that the proposed research could not practicably be conducted without access to and use of the protected health information, the IRB will limit the scope of the protected health information the investigator may obtain and use pursuant to the waiver the minimum amount necessary for the research purpose. The Privacy Rule permits Covered Entity to reasonably rely on the fact of the IRB’s approval of waiver, in conjunction with the IRB’s description of the data needed, in satisfaction of the Privacy Rule requirement that Covered Entity disclose only the minimum amount of protected health information necessary to accomplish the purpose of the disclosure.
 - Applicable state health information privacy laws may require the IRB to determine that additional criteria have been satisfied before approving a request for alteration to or waiver of authorization, or may not permit waiver in certain instances. The IRB will ensure that its decision to waive authorization, in whole or in part, is consistent with the requirements of applicable state law (including laws and regulations relating to DNA analysis, HIV status, and treatment in a substance abuse program).
 - The investigator’s use of participants’ protected health information pursuant to a waiver of authorization must be study or protocol-specific. The IRB will not approve a waiver request that will permit the investigator or other authorized recipient to use participants’ protected health information for any other research purpose, including population of a research database or repository for re-analysis, that is not part of the original protocol. Through waiver, however, the IRB may authorize the investigator and other data recipients to remove information that identifies participants and to use and disclose the resulting information for any purpose permitted by law, including for other research purposes. ***Documentation of Waiver***
 - Where the IRB determines that the criteria for waiver have been met, the IRB will document its decision in the minutes and in the protocol determination letter provided to the investigator. The documentation will, at a minimum:
 - identify the IRB and the date on which waiver of authorization was approved;

- state that the IRB has determined that the waiver satisfies the criteria set forth above;
 - describe the nature and scope of the waiver;
 - briefly describe the protected health information for which use or disclosure has been determined to be necessary;
 - state whether the waiver request was reviewed and approved under normal or expedited review procedures as set forth by the Common Rule; *and*
 - if expedited review procedures were used, signed by the IRB chairperson or other IRB member designated by the chairperson.
- A template for documentation of waiver is attached as Appendix B.
 - The Covered Entity must retain a copy of the waiver document for a minimum of six (6) years from the signature date or when the study participants' protected health information was last used or disclosed pursuant to the waiver, whichever is later.

Acceptance of Third Party Waivers

Where review of a protocol for a multi-site research trial for purposes of the Common Rule will be conducted by each institutional review board associated with an institution where data will be collected, the Privacy Rule permits a waiver of authorization to be granted by that review board, or by a separate institutional review board or privacy board. If Covered Entity has accepted a waiver of authorization issued by another review board, the IRB will obtain a copy of such waiver for its files for any protocol for which it is responsible under the Common Rule.

Accounting of Disclosures

Covered Entity is responsible for tracking and accounting for all disclosures of protected health information pursuant to authorization waived in whole or in part by the IRB. To facilitate Covered Entity's compliance with this requirement of the Privacy Rule, the IRB will require the investigator to prepare a completed Record of Disclosure of Patient Information for Research Purposes (Attachment 45) in substantially the same form as the example attached as Appendix F (with the date(s) of disclosure left blank). For paper files, a copy may be placed in each record reviewed; analogous procedures may be used to annotate electronic records reviewed. The investigator must provide Covered Entity with a completed copy of such a record for each disclosure of a patient's protected health information by Covered Entity to the investigator pursuant to the waiver. Where periodic disclosures of data regarding the same patient will be made over time, the accounting may provide the dates of the first and last disclosure, and the periodicity or frequency of such disclosures.

CROSS REFERENCES:

Policy 2.1 (Authorization to Use and Disclose Protected Health Information)

Policy 2.3 (Data Use Agreement for Limited Data Set)

Appendix B (Template for Documentation of Alteration to or Waiver of Authorization to Use or Disclose Protected Health Information for Research Purposes)

Appendix F (Template for Record of Disclosure of Health Information for Research Purposes – Attachment 45)

SUBJECT: Use or Disclosure of Limited Data Set Pursuant to Data Use Agreement

POLICY STATEMENT: When an investigator proposes to conduct research analyzing protected health information maintained by or on behalf of Covered Entity, the IRB will consider whether use of a limited data set may be sufficient for the research purpose. Even where informed consent will be waived under the Common Rule, a data use agreement is preferable to a waiver of authorization for purposes of meeting the requirements of the Privacy Rule, as the former is more protective of patient privacy and does not require an accounting of disclosures by the Covered Entity. An investigator who proposes to conduct data research shall be asked to document why a limited data set of protected health information is not appropriate for the research purpose. This Policy covers the specific content requirements for data use agreements.

APPLICABLE LAW: 45 C.F.R. § 164.514(e)

PROCEDURES FOR IMPLEMENTATION: The IRB will review proposed data use agreements and limited data sets in accord with the following standards.

Content Requirements

- The data use agreement must, at a minimum:
 - (1) Establish the permitted uses and disclosures of the limited data set by the investigator, which may be only for the purposes of the investigator's research, public health activities, and the Covered Entity's health care operations;
 - (2) Provide that the investigator will:
 - (a) not use or further disclose the limited data set other than as permitted by the data use agreement or as otherwise required by law;
 - (b) use appropriate safeguards to prevent any use or disclosure of the information other than as provided for by the data use agreement;
 - (c) report to Covered Entity any use or disclosure of the information not provided for by the agreement of which the investigator becomes aware;
 - (d) ensure that any agents, including subcontractors, to whom it provides the limited data set agree to the same restrictions and conditions that apply to the investigator with respect to such information; *and*
 - (e) not identify or contact the research participants.

There is no required form of data use agreement, but the agreement must at a minimum address each of the elements set forth above. The IRB may require that the data use agreement include additional restrictions on the investigator's ability to use and disclose the limited data set or impose additional obligations on the investigator with respect to such

information if the IRB determines that such restrictions or obligations are warranted given the sensitivity of the information and/or the nature of the research.

A data use agreement template is attached as Appendix C.

Parties to the Agreement

- Where the investigator is a member of the Covered Entity workforce, the data use agreement is between the workforce member and Covered Entity and may take the form of an employee confidentiality agreement which includes the data use agreement provisions.
- The HSRO on behalf of the IRB will forward the investigator's signed data use agreement to the appropriate person(s) authorized to sign the agreement on behalf of the Covered Entity.

The Limited Data Set

- The data made available under a data use agreement must be the minimum necessary for the purposes. For this purpose, the IRB shall evaluate the identifiers sought by the investigator for the research purpose, including each of the fields listed in the definition of protected health information. The limited data set of information may *not* under any circumstances include any of the following identifiers of a participant or of a participant's relatives, household members, or employer(s):
 - names;
 - street address information other than city, state, and zip code;
 - telephone and fax numbers;
 - e-mail, internet, and web addresses;
 - Social Security numbers;
 - medical record and prescription numbers;
 - health plan beneficiary numbers;
 - account numbers;
 - certificate/license numbers;
 - vehicle identifiers and serial numbers;
 - device identifiers and serial numbers;
 - biometric identifiers; and
 - full face photographic and comparable images

The IRB will not approve a proposed data use agreement pursuant to which the investigator seeks to obtain more information than is necessary for the research purpose.

- The term "device identifier" is not defined by the Privacy Rule and is not a term of art recognized by the Food and Drug Administration (FDA). Where information about a

medical device will be included in a limited data set, the IRB shall consider whether there is a reasonable basis to believe that the information about the device, when used in accord with the data use agreement, could be used to identify the individual.

- An investigator may propose that Covered Entity will disclose study participants' protected health information to a third party to create the limited data set to be used for the research. The IRB will approve such a protocol only on the condition that the third party provides a copy of a valid business associate agreement with the Covered Entity for such purpose.

Accounting of Disclosures

Neither Covered Entity nor the investigator is required to record or account for disclosures of limited data sets of protected health information pursuant to a data use agreement that satisfies the requirements of this Policy 2.3.

CROSS REFERENCES:

Policy 2.1 (Authorization to Use and Disclose Protected Health Information for Research)

Appendix C (Template for Data Use Agreement for Disclosure of a Limited Data Set for Research Purposes)

SUBJECT: Review of Exempt Research

POLICY STATEMENT: Although not subject to IRB review for purposes of the Common Rule, exempt research must be conducted in compliance with the Privacy Rule to the extent that research involves the creation or receipt of protected health information about patients of Covered Entity or the use or disclosure of protected health information maintained by or on behalf of Covered Entity. An investigator who seeks to conduct exempt research involving protected health information must: (1) obtain from each research participant (or the participant's legal representative) a signed, written authorization to use and disclose the participant's protected health information for the research purpose; (2) obtain documentation of IRB waiver of authorization to use and disclose participants' protected health information for the research purpose; *or* (3) enter into a data use agreement with Covered Entity which permits the investigator to conduct research using a limited data set of protected health information. Thus, despite the fact that research is not subject to IRB review under the Common Rule, the IRB may receive requests to review the research for the purpose of approving an authorization or granting a waiver of authorization under the Privacy Rule. Refer to the UM IRB policies and procedures related to exempt research.

PROCEDURES FOR IMPLEMENTATION:

- IRB will review authorizations in accord with Policy 2.1.
- IRB will review investigators' requests for waiver of authorization, in whole or in part, in accord with Policy 2.2, including provisions necessary to provide an accounting of disclosures.
- IRB will review data use agreements in accord with Policy 2.3.
- IRB will review proposals involving representations regarding the vital status of individuals in accord with Policy 3.1.

CROSS REFERENCES:

Policy 2.0 (Provision of Research Data to Investigators and/or Third Party Sponsors)

SUBJECT: Research with Decedents' Information

POLICY STATEMENT: Although research involving deceased persons is not subject to IRB review under the Common Rule, decedents' protected health information is subject to the Privacy Rule. An investigator who seeks to conduct research using decedents' protected health information maintained by or on behalf of Covered Entity must: (1) obtain from the decedent's legal representatives signed, written authorization to use and disclose the protected health information for the research purpose; (2) obtain documentation of IRB waiver of authorization to use and disclose the protected health information for the research purpose; (3) enter into a data use agreement with Covered Entity which permits the investigator to conduct the research using a limited data set of the decedents' protected health information; *or* (4) make certain written representations to Covered Entity regarding the need for the decedents' information.

APPLICABLE LAW: 45 C.F.R. § 164.512(i)(1)(iii)

PROCEDURES FOR IMPLEMENTATION:

Where an investigator elects not to use a data use agreement, authorization, or waiver of authorization, the IRB will review the investigator's proposed written representation to ensure that it satisfies the requirements of this Policy 3.1.

Content of Representation

- The investigator must represent in writing that:
 1. access to the requested information about the deceased persons is sought solely for the purpose of research on that information; *and*
 2. the requested information is necessary for the research purpose.
- In approving a representation, the IRB will limit the scope of decedents' protected health information that the investigator may obtain to the minimum amount necessary for the research purpose. The Privacy Rule permits Covered Entity to reasonably rely on the certification in satisfaction of the Rule's requirement that Covered Entity disclose only the minimum amount of protected health information necessary to accomplish the purpose of the disclosure.
- At its option, the IRB (or Covered Entity) may elect to require the investigator to provide evidence that the proposed data subjects are deceased. For example, a list of subjects for whom data is sought may have been culled from county records.
- A template for investigator representations is attached as Appendix E.

Accounting of Disclosures

Covered Entity is responsible for tracking and accounting for all disclosures by it of decedents' protected health information pursuant to an investigator representation. To facilitate Covered Entity's compliance with this requirement of the Privacy Rule, the IRB will require the investigator to prepare a completed Record of Disclosure of Health Information for Research Purposes (Attachment 45) in substantially the same form as the example attached as Appendix F (minus date(s) of disclosure). The investigator must provide Covered Entity with a copy of such a record for each disclosure of a decedent's protected health information pursuant to the investigator certification.

CROSS REFERENCES:

Appendix E (Template for Investigator Representation for Research with Decedents' Information)

Appendix F (Template for Record of Disclosure of Health Information for Research Purposes)

SUBJECT: Research with Biological Materials and Tissues

POLICY STATEMENT: Biological materials and tissues are not in themselves protected health information under the Privacy Rule. However, protected health information accompanying such materials and tissues renders them subject to the Privacy Rule. All research performed using biological materials or tissues that are *accompanied by protected health information* and are maintained by or on behalf of, or created about or received from patients of, Covered Entity shall be conducted consistent with this Policy.

PROCEDURES FOR IMPLEMENTATION: Research to be performed using biological materials or tissues accompanied by protected health information and created about or received from patients of Covered Entity, or maintained by or on behalf of Covered Entity, shall be reviewed and conducted in accord with applicable standards of Policy 2.0.

CROSS REFERENCES:

Policy 2.0 (Provision of Research Data to Investigators and/or Third Party Sponsors)

SUBJECT: Creation and Use of Institutional Research Databases and Repositories

POLICY STATEMENT: The development of databases and repositories of protected health information for future research is considered “research” under the Privacy Rule and requires: (a) authorization of the individuals to whom the information refers which specifically permits the inclusion of the data in the database or repository; (b) IRB-approved waiver of authorization; *or* (c) a data use agreement between Covered Entity and the investigator for the use of a limited data set for research purposes.

PROCEDURES FOR IMPLEMENTATION:

- Investigators and the IRB shall refer to Policy 5.1 for guidance on the creation and population of research databases and repositories of protected health information at Covered Entity.
- Investigators and the IRB shall refer to Policy 5.2 for guidance on the subsequent use of the information in such databases and repositories.

CROSS REFERENCES:

Policy 5.1 (Institutional Research Databases and Repositories—Population of Databases and Repositories)

Policy 5.2 (Institutional Research Databases and Repositories—Use of Protected Health Information in Databases and Repositories)

SUBJECT: Institutional Research Databases and Repositories—Population of Databases and Repositories

POLICY STATEMENT: This Policy sets forth the requirements investigators must satisfy to create a research database or repository.

PROCEDURES FOR IMPLEMENTATION:

- An investigator who seeks to populate a research database or repository with protected health information will:
 - (a) obtain written authorization of the individual to whom the information refers, which shall have been approved by the IRB in accordance with Policies 2.1 which specifically permits the inclusion of the protected health information in a research database or repository;
 - (b) obtain IRB waiver of authorization in accordance with Policies 2.2 which specifically permits the inclusion of the protected health information in a research database or repository; *or*
 - (c) enter into a data use agreement with Covered Entity, which shall have been approved in accordance with Policy 2.3, that permits the investigator to use a limited data set of participants' protected health information for research purposes, including for the development of databases or repositories.
- The proposed uses of a database or repository that is described in the authorization or waiver of authorization need not be overly specific, provided that the other requirements for Authorization or its Waiver are satisfied.

CROSS REFERENCES:

Policy 2.1 (Review of Interventional Research—Authorization to Use and Disclose Protected Health Information)

Policy 2.2 (Review of Interventional Research—Waiver of Authorization to Use and Disclose Protected Health Information)

SUBJECT: Institutional Research Databases and Repositories—Use of Protected Health Information in Databases and Repositories

POLICY STATEMENT: This Policy covers the use of information in a research database or repository for subsequent research purposes. The requirements that must be met to obtain and use information in a database or repository vary depending on where the database or repository is maintained.

*This Policy does **not** affect the use of databases containing only: (i) information to be used solely for treatment purposes; or (ii) de-identified information (see UM IRB Privacy and Security Policy) for procedures for de-identifying patient information).*

PROCEDURES FOR IMPLEMENTATION:

- In accordance with current institutional policies, an investigator must submit a request to the IRB for access to data in any research databases and repositories. The IRB shall review the request in accord with the terms of the institution's policies and procedures, its assurance with the Department of Health and Human Services (HHS) and applicable federal and state laws and guidance.
- *If the database or repository is maintained within the Covered Entity's Health Care Component (generally, a clinical database or record maintained in part for treatment purposes), an investigator **also** must obtain new patient authorization(s) or a new waiver of authorization that specifically permits access to and use of the information in the database or repository for a specific research purpose. The IRB will condition access to protected health information in a Covered Entity-maintained database or repository on satisfaction of this requirement. This requirement does not apply if the database or repository is maintained outside of the Covered Entity's Covered Health Care Component.*

CROSS REFERENCES:

Policy 2.2 (Review of Interventional Research—Waiver of Authorization to Use and Disclose Protected Health Information)

SUBJECT: Transition Rule

POLICY STATEMENT: Policies 1.0-5.2 do *not* apply with respect to research using protected health information maintained by or on behalf of, or created about or received from patients of, Covered Entity, if *prior to* April 14, 2003, the investigator has obtained—

- (a) an IRB-approved research informed consent from each participant in the study;
- (b) an IRB waiver of informed consent in accordance with the Common Rule; *or*
- (c) an authorization or other express legal permission from each participant in the study to use or disclose the participant’s protected health information for the research.

However, Covered Entity and the investigator may use and disclose the protected health information only to the extent and for the purpose(s) permitted by (a), (b), or (c) (whichever is applicable). Furthermore, if the investigator seeks to obtain from an existing study participant on or after April 14, 2003, a new or revised informed consent, the investigator may not access, use, or disclose that participant’s protected health information without obtaining authorization or waiver of authorization consistent with the Privacy Rule.

PROCEDURES FOR IMPLEMENTATION:

- If prior to April 14, 2003, (a), (b), or (c), above, has or will have been satisfied with respect to a particular protocol, the IRB need review that protocol only as required by and consistent with the Common Rule and other applicable human subject research protection laws and regulations.
- With respect to active studies already reviewed by the IRB and for which none of (a)-(c), above, will have occurred prior to April 14, 2003, the IRB will need to re-review these studies prior to that date in accordance with Policies 1.0-5.2, as applicable.
- If a protocol has been approved by the IRB before April 14, 2003, but enrollment has not closed, the investigator may not access, use, or disclose patient information about any participant who signs an informed consent on or after that date without also obtaining written HIPAA authorization or IRB waiver of authorization. The investigator must submit a new Research Protocol Application to the IRB for review with respect to uses and disclosures of these participants’ information.

Appendix A

Template for Authorization to Use and Disclose Protected Health Information for Research Purposes

[forms are on the IRB web page, www.hsro.miami.edu/hipaa]

Appendix B

Example Template for Documentation of Alteration to or Waiver of Authorization to Use or Disclose Protected Health Information for Research Purposes

STATEMENT OF APPROVAL OF [ALTERATION/WAIVER] [TO/OF] AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION

To Custodian of Patient Information: Federal privacy standards issued by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") permit the University of Miami to use or disclose to an investigator patient information pursuant to documentation of [waiver of/alteration to] patient authorization by an Institutional Review Board (45 C.F.R. § 164.512(i)). This Statement satisfies the HIPAA requirement for documentation of [waiver of/alteration to] patient authorization.

On _____ 2003, the University of Miami Institutional Review Board (the "Board") approved a request to [waive/alter] the HIPAA patient authorization requirement to permit the [use/disclosure] of patient protected health information [by/to] [Investigator's name] for purposes of [conducting the study entitled (name of study) / developing a research protocol / evaluating the a University health care facility as a potential research site / identifying prospective research participants / contacting prospective research participants].

The Board reviewed the [waiver/alteration] request under [normal/expedited] review procedures in accord with the requirements of federal human subject protection regulations and, having determined that the criteria set forth at 45 C.F.R. § 164.512(i)(2)(ii) have been met, approved [the waiver request in accord with these procedures / alteration of the authorization requirement as follows: (Describe nature of alteration)].

In approving the [waiver /alteration], the Board has determined that [access/use] by [investigator's name] [to/of] the following information is necessary for the purpose(s) described above: [describe nature and scope of protected health information to be used or disclosed; use attachment if necessary].

The scope of the Board's [waiver of/alteration to] authorization is limited solely to this information.

Please contact [contact person] with the Board staff should you have any questions regarding this statement.

Signature of Board Chairperson (or Designee)

Date

Name

Title

University of Miami Institutional Review Board

Appendix C

Template for Data Use Agreement for Disclosure of a Limited Data Set for Research Purposes

DATA USE AGREEMENT

This Data Use Agreement (“Agreement”), effective as of _____, 2003 (“Effective Date”), is entered into by and between [*Recipient*] and the [*University of Miami / Jackson Health System /name of other Covered Entity from which the limited data set will be obtained -- select appropriate party*] (the “Covered Entity”) (each a “Party” and collectively the “Parties”). The purpose of this Agreement is to provide [*Recipient*] with access to a Limited Data Set (“LDS”) of Patient Information for use in its Research activities in accord with the HIPAA Regulations.

1. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the “HIPAA Regulations” codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.
2. Preparation of the LDS. The Covered Entity shall prepare and furnish to [*Recipient*] a LDS in accord with the HIPAA Regulations.
3. Minimum Necessary Data Fields in the LDS. In preparing the LDS, the Covered Entity will include the data fields specified in Attachment A, which are the minimum fields necessary to accomplish the purposes set forth in Section 5 of this Agreement.
4. Responsibilities of [Recipient]. [*Recipient*] agrees to:
 - a. Use or disclose the LDS only as permitted by this Agreement or as required by law;
 - b. Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;
 - c. Report to the Covered Entity any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;
 - d. Require any of its subcontractors or agents that receives or has access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to [*Recipient*] under this Agreement; and
 - e. Not use the information in the LDS to identify or contact the individuals who are data subjects.
5. Permitted Uses and Disclosures of the LDS. [*Recipient*] may use and/or disclose the LDS for its Research activities.
6. Term and Termination.

- a. Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as [Recipient] retains the LDS, unless terminated sooner as set forth in this Agreement.
- b. Termination by [Recipient]. [Recipient] may terminate this agreement at any time by notifying the University of Miami and returning or destroying the LDS.
- c. Termination by the Covered Entity. The Covered Entity may terminate this agreement at any time by providing 30 days prior written notice to [Recipient].
- d. For Breach. The Covered Entity shall provide written notice to [Recipient] within 10 days of any determination that [Recipient] has breached a material term of this Agreement. The Covered Entity shall afford [Recipient] an opportunity to cure said alleged material breach on mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within 30 days shall be grounds for the immediate termination of this Agreement by the Covered Entity.
- e. Effect of Termination. Sections 1, 4, 5, and 7 of this Agreement shall survive any termination of this Agreement under subsections 6(c) or 6(d).

7. Miscellaneous.

- a. Change in Law. The Parties agree to negotiate in good faith to amend this Agreement to comport with changes in applicable federal law that materially alter either or both Parties' obligations under this Agreement; provided, however, that if the Parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law, either Party may terminate this Agreement as provided in section 6.
- b. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.
- c. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the Parties and their respective successors or assigns any rights, remedies, obligations, or liabilities whatsoever.
- d. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- e. Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing, or enforcing any of the provisions of this Agreement.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

Covered Entity

By: _____

Print Name: _____

Print Title: _____

Date: _____

[RECIPIENT]

By: _____

Print Name: _____

Print Title: _____

Date: _____

Appendix D

Template for Investigator Representation for Reviews Preparatory to Research

**INVESTIGATOR'S REPRESENTATION
REVIEW OF PATIENT INFORMATION FOR RESEARCH PREPARATION PURPOSES**

To Custodian of Patient Information: Federal privacy standards issued by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") permit the University of Miami to make patient information available for review by an investigator for protocol development and participant screening purposes, provided that the following representations are obtained from the investigator (45 C.F.R. § 164.512(i)(1)(ii)).

1. Purpose(s) for which access to patient records maintained by the Covered Entity is(are) sought (check all that apply):

protocol development *and/or* identification of potential research participants

2. Describe the nature and scope of the patient information to which access is sought:

3. Investigator represents that:

- (a) access to the requested patient information is sought *solely* for the purpose(s) indicated above;
- (b) the requested patient information is *necessary* for the purpose(s) indicated above; and
- (c) no individually identifiable patient information will be copied by Investigator or removed from the Covered Entity's premises during the course of or following the review.

Signature

Date

Name

Title and Institutional Affiliation

Appendix E

Template for Investigator Representation for Research with Decedents' Information

INVESTIGATOR'S REPRESENTATION ACCESS TO DECEASED PATIENTS' INFORMATION FOR RESEARCH PURPOSES

To Custodian of Patient Information: Federal privacy standards issued by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) permit the University of Miami to disclose deceased patients' health information to an investigator for research purposes, provided that the following representations are obtained from the investigator (45 C.F.R. § 164.512(i)(1)(iii)).

1. Describe the nature and scope of the deceased patients' information to which access is sought:

2. Investigator represents that:

- (a) access to the requested information about deceased patients is sought *solely* for the purpose of research on the information; and
- (b) the requested patient information is *necessary* for the research purpose.

Signature

Date

Name

Title and Institutional Affiliation

Appendix F

Template for Record of Disclosure of Protected Health Information

Attachment 45 – Accounting for Disclosures

[NOTE: FORM FOUND AT www.hsro.miami.edu/hipaa]

