

SUNY DOWNSTATE MEDICAL CENTER
UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE

Subject: <u>USES AND DISCLOSURES FOR RESEARCH PURPOSES</u>	No. HIPAA-28
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I. PURPOSE

To ensure that all uses and disclosures of protected health information (PHI) for research purposes complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its accompanying regulations.

II. POLICY

In addition to the requirements delineated in this policy, all research activities must also comply with other applicable policies addressing the requirements of the Common Rule, FDA, provision of healthcare and special categories of information (ie, genetic tests, HIV, alcohol and substance abuse, psychotherapy notes and mental health information).

III. DEFINITION(s)

None

IV. RESPONSIBILITIES

It is the responsibility of all medical staff members and hospital staff members to comply with this policy. Medical staff members include physicians as well as allied health professionals. Hospital staff members include all employees, medical or other students, trainees, residents, interns, volunteers, consultants, contractors and subcontractors at the hospital.

The development of the procedure section is the responsibility of the respective department. It is dependent upon the unique needs of each department's operating structure and shall be advanced and customized accordingly.

V. PROCEDURE/GUIDELINES

A. Research Not Requiring Subject Authorization- Under the following circumstances, uses and disclosures for research purposes are permitted without the subject's authorization.

1. Reviews Preparatory to Research- The use and disclosure of PHI is permitted to develop a research protocol or for similar purposes preparatory to research (Ex: To determine whether there is participant information that would meet the study eligibility criteria).
 - a. The Principal Investigator (PI) must represent that (See attached Researcher Certification for Reviews Preparatory to Research):
 - i. The use or disclosure is sought solely to prepare a research protocol or for similar purposes preparatory to research;
 - ii. No researcher will remove the PHI from SUNY Downstate premises in the course of the review; and
 - iii. The PHI for which use or disclosure is sought is necessary for the research purpose.
 - b. During the preparatory review, those granted access may only record information in a de-identified format. See policy on De-identification of Information.
 - c. Once the PI has determined to go forward with the study, the continued use or disclosure of PHI is not permitted without an authorization.
2. Research on Decedent's Information
 - a. The PI must represent that (See attached Researcher Certification for PHI of Decedents):
 - i. The use or disclosure is sought solely for research on the PHI of decedents; and
 - ii. The PHI for which use or disclosure is sought is necessary for the research purpose.
 - b. The PI must provide documentation, at the request of the Research Foundation, of the death of any subject about whom information is sought.

Please note that PHI of an individual who has been deceased for more than 50 years is not considered PHI and is no longer covered under the HIPAA Privacy Rule.

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3. IRB/ Privacy Board Approval of Waiver- Uses and disclosures of PHI for research purposes are permitted if the IRB/ Privacy Board grants a partial or total waiver of the authorization requirement. If only a partial waiver has been granted, the use or disclosure must be conditioned upon compliance with any authorization requirements that were not waived.
 - a. Membership Composition- The IRB/ Privacy Board members must separately consider their roles as privacy guardian under HIPAA and overall welfare guardian under other laws and IRB policies.
 - i. Members must have various backgrounds and appropriate professional competency to review the effect of the protocol on the subject's privacy rights and related interests;
 - ii. The Board must include one member who is not affiliated with SUNY Downstate, any entity conducting or sponsoring the research and not related to any person affiliated with these entities or with SUNY Downstate.
 - iii. The Board cannot have any members with a conflict of interest.
 - b. Waiver Criteria- The IRB/ Privacy Board should keep minutes of its meetings documenting that the requested waiver satisfies each of the following criteria:
 - i. The use or disclosure involves no more than a minimal risk to the privacy of the subjects because:
 - There is an adequate plan to protect the "identifiers" from improper use or disclosure (See policy on De-Identification of Information for the types of information considered to be "identifiers");
 - There is an adequate plan to destroy the "identifiers" at the earliest opportunity, unless there is a health or research justification for retaining the "identifiers" or their retention is required by law; and
 - There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study or for other research for which the use or disclosure of PHI is otherwise permitted under this policy.
 - ii. The research could not practicably be conducted without the waiver- Research involving treatment will almost never be eligible since most clinical trials could practicably be conducted without a waiver; and
 - iii. The research could not practicably be conducted without access to and use of the PHI- If de-identified information or a limited data set can practicably be used, a waiver of authorization should not be granted.
 - c. Review Procedures- The IRB/ Privacy Board must follow the Common Rule's normal or expedited review procedures, as applicable.
 - i. The proposed research must be reviewed at convened meetings at which a majority of the members are present, including at least one member meeting the criteria of Section III.A.3.a.ii.
 - ii. The waiver must be approved by the majority of the members present at the meeting; and
 - iii. If it is elected to use an expedited review, the research may not involve no more than a minimal risk to the privacy of the relevant

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subjects. The review and approval of the waiver may be carried out by the chair or one of the chair's designated board members.

- d. Documentation of Waiver- The documentation must include a:
 - i. Statement identifying the IRB/ Privacy Board;
 - ii. Date on which the waiver was approved;
 - iii. Statement that the IRB/ Privacy Board has determined that the waiver satisfies the required criteria;
 - iv. Brief description of the PHI that the IRB/ Privacy Board has determined is necessary for research purposes;
 - v. Statement that the waiver has been reviewed and approved under either normal or expedited review procedures and that all applicable procedures were followed; and
 - vi. Signature of the IRB/ Privacy Board chair or other member, as designated by the chair.
4. De-Identified Information- De-identified information that complies with the policy on De-identification of Information may be used or disclosed for research purposes without restriction.
5. Limited Data Sets- Uses and disclosures for research purposes of a limited data set including partially de-identified information is permitted, without an authorization, if it complies with the policy on Uses of Limited Data Sets.

B. Research Requiring Subject Authorization- For all other uses and disclosures for research purposes, the subject must provide a HIPAA authorization for such purpose. SUNY DMC's IRB Consent Template includes the relevant HIPAA authorization requirements. Therefore, by obtaining subject consent to participate in the research study, the PI will also be able to obtain the subject's HIPAA authorization for the use and disclosure of PHI.

1. The subject's ability to receive research- related treatment as part of the research study may be conditioned upon the subject's agreement to sign the authorization form; however, failure to sign cannot limit access to treatment available outside of the study.
2. Conditioned authorizations (research- related treatment is dependent on subject's authorization) and unconditioned authorizations (i.e. corollary research activity such as creation of central research database or tissue banking repository) for research may be combined on the same form, provided that the authorization clearly differentiates between the conditioned and unconditioned components and clearly allows the subject the option to opt in to the unconditioned research activities.
 - a. A separate check- box for the unconditioned research activity should be utilized with a distinct signature line to signify that the subject has opted in to the unconditioned research activity and authorizes optional research that does not affect the research related treatment.
 - b. The only exception to this provision is for research that involves the use or disclosure of psychotherapy notes. An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes.

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3. Although every HIPAA authorization form must include a 'purpose'; an authorization for the use and disclosure of PHI for research purposes does not have to be study specific. For future research purposes, the authorization form must adequately describe such purpose so that it would be reasonable for the subject to expect that his/ her PHI could be used or disclosed for such future research. This could include specific statements with respect to sensitive research to the extent such research is being contemplated.
 - a. The requirements delineated under Section V.B.2. must be met.
 - b. The statement must include the recipients of the future research even if it is generalized into a particular "class of persons".
 - c. The description of the PHI to be used for the future research may include information collected beyond the time of the original study.
4. The PI must submit the IRB consent form containing the HIPAA authorization to the IRB Committee for its approval before any PHI is obtained.
5. Subjects may revoke the authorization at any time; however, the PHI that was obtained may continue to be used, as necessary, to maintain the integrity of the research study (Ex: To report adverse events, conduct investigations of scientific misconduct).
 - a. If a subject signs a combined authorization for conditioned and unconditioned research activities and later specifically revokes only the unconditioned research activity (i.e. tissue banking component), SUNY DMC may continue to act in reliance of the authorization for the conditioned component (i.e. the clinical trial).
 - b. If it is not clear exactly to which research activities the subject's revocation applies, written clarification should be obtained from the subject in order for the revocation to apply to only certain research activities. If such clarification cannot be obtained, the entire authorization must be treated as revoked.

C. Special Categories of Information- Additional guidelines are delineated in the policies on Alcohol and Substance Abuse Information, HIV- Related Information and Mental Health Information. This information pertains only to uses and disclosures for research purposes. Information that is completely de-identified or meets the requirements of a limited data set, in accordance with their respective policies, would not require the restrictions specified below.

1. Genetic Information

- a. For genetic testing of human biological samples for which a research authorization is obtained, the subject must also sign a specific consent form for genetic testing under NY Civil Rights Law §79-1(2)(b). Otherwise, testing is only permissible if either:
 - i. The tissue sample is anonymous, the research protocol has been approved by an IRB and the research protocol assures the anonymity of the sample sources; or
 - ii. The subject has signed a general consent form for the use of the sample for research purposes under NY Civil Rights Law §79-1(9)(a), the sample is either permanently stripped of identifying information or is coded in accordance with an IRB-approved coding methodology and the research protocol has been approved by an IRB.
- b. The disclosure of information about a subject derived from genetic tests performed in stored human tissue or linking a subject with specific results of

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genetic tests to an organization or person (including sponsors and researchers) is permitted if the subject signed either a valid research authorization form or a Consent to Release Genetic Information form under NY Civil Rights Law §§79-1(3)(a) and 79-1(9)(d).

2. HIV-Related Information

a. Definition of HIV-related Information

- i. Information that is in the possession of a person who provides health or social services or who obtains the information pursuant to a release of confidential HIV-related information and concerns whether an individual has been the subject of an HIV-related test, has an HIV infection, HIV-related illness or AIDS; or
- ii. Information that identifies or reasonably could identify an individual as having one or more of such conditions, including information pertaining to such person's contacts.

b. Disclosure of HIV- related information is permitted without an authorization if the disclosure is permitted pursuant to Section III.A. of this policy and the disclosure is either to a(n):

- i. Health facility or healthcare provider in relation to the procurement or use of a human body or body part, including organs, tissues, blood, semen or other body fluids, for use in research; or
- ii. Employee or agent of SUNY Downstate, if:
 - The employee/ agent is permitted to access medical records;
 - SUNY Downstate is authorized by law to obtain the HIV-related information; and
 - The employee/ agent either provides healthcare to the protected individual or maintains or processes medical records for billing or reimbursement.

c. Researchers should make every effort to obtain a NY Release of Confidential HIV-Related Information form from the subject upon first contact with the subject.

3. Alcohol and Substance Abuse- These restrictions apply to all alcohol and substance abuse treatment information maintained by SUNY Downstate and its clinics. They do not apply to any numbers assigned to a patient by a treatment program as long as the numbers cannot be used to identify a patient with reasonable accuracy and speed from sources external to the treatment program.

a. When obtaining a research authorization from the patient, a PHSA consent must be obtained, as well.

b. Disclosure of alcohol and substance abuse information without an authorization is permitted if the disclosure is permitted under Section III.A. of this policy and the director of the treatment program determines that the recipient of the patient information:

- i. Is qualified to conduct research;
- ii. Has a research protocol under which the patient information will be maintained in a secure room, locked file cabinet, safe or other similar container when not in use;
- iii. Has a research protocol under which the patient information will not be re-disclosed to other than SUNY Downstate and under which

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- patient information will not be revealed in any report generated by the researcher; and
- iv. Has provided a satisfactory written statement that a group of three or more individuals, independent of the research project, reviewed the protocol and determined that the rights and welfare of patients will be adequately protected and the risks of disclosing patient information are outweighed by the potential benefits of the research.
- c. The researcher may only re-disclose such information back to the treatment program and may not identify any individual patient in reports or disclosures.

4. Mental Health Information

- a. Definition of Mental Health Information- Clinical records or clinical information tending to identify patients who are receiving or have received mental health treatment or care.
- b. Mental health information may be released pursuant to a valid research authorization.
- c. Mental health information may be released without a valid research authorization only if the release is permitted pursuant to Section III.A. of this policy and:
 - i. The Mental Health Director (ie. Director of the ward, floor or clinic providing mental health services and would be the individual who currently has oversight of the mental health services) consents to the release; and
 - ii. The release is to qualified researchers requiring mental health information for a particular research project who have obtained appropriate approval from an IRB or from another committee specially constituted for the approval of research projects at SUNY Downstate involving mental health information.
- d. All disclosures of mental health information for research purposes must be limited to the minimum necessary for the research purpose.
- e. The researcher may not re-disclose mental health information to research sponsors, contract research organizations or any other person or organization without the prior approval of the IRB Committee.

D. Subject Recruitment- In order to effectively recruit subjects into an IRB- approved study, the PI may provide the study eligibility criteria to individual SUNY Downstate clinicians and request that patients meeting such criteria be referred to the PI for the purpose of research recruitment. The SUNY Downstate clinician must obtain a signed "Subject Recruitment Authorization Form" from the patient before disclosing any information to the PI. This form ensures that the patient is aware of the PI's name, department and research study, as well as the specific information that will be disclosed, for the purpose of receiving contact and additional information about the particular study.

Alternatively, in those situations where the patient is not physically present and it is impracticable for the SUNY Downstate clinician to obtain the patient's written authorization to disclose his/ her information to the PI for research recruitment purposes, the SUNY Downstate clinician may document the patient's verbal authorization on the "Subject Recruitment: Physician's Documentation of Patient's Verbal Authorization" form. The SUNY Downstate clinician must certify that s/he discussed specifically delineated information with the patient and has received the patient's authorization to

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disclose his/her information for this purpose. However, in instances where HIV, mental health or alcohol/ drug abuse information may be included in such disclosure, a verbal authorization is not permissible. In addition, patients who did not receive services at DMC sites (ie. services were provided at Kings County Hospital Center locations) may not provide such verbal authorization.

The PI is responsible for maintaining the Subject Recruitment Authorization Forms and the Subject Recruitment: Physician's Documentation of Patient's Verbal Authorization forms in his/ her corresponding study files.

E. Disclosures to DOH- Disclosures to the Department of Health for scientific studies and research is permitted under the following circumstances, as long as the minimum necessary standards are met (See policy on Minimum Necessary Guidelines):

1. The subject authorizes the disclosure.
2. An IRB/ Privacy Board waives the authorization.

F. Subject Access- Subjects generally have a right to access all of their PHI maintained by SUNY Downstate or its business associate. Subjects' access rights may be temporarily suspended while a clinical trial is in progress, provided that the subject agreed to this denial when consenting to participate in the clinical trial. Subjects requesting access should be referred to the Health Information Management Department, in accordance with the policy on Patient Requests for Access.

G. Accounting of Disclosures

1. All disclosures for research purposes must be documented as delineated in the policy on Accounting of Disclosures. The following disclosures are exempted from this requirement:
 - a. Disclosures made pursuant to the subject's authorization;
 - b. Disclosures made pursuant to the policy on De-Identification of Information; and
 - c. Disclosures made pursuant to the policy on Use of Limited Data Sets.
2. Research disclosures- For research activities that received a waiver of patient authorization and involve 50 or more individuals, an abbreviated accounting can be provided. The researcher should coordinate the provision of this accounting with the Health Information Management Department:
 - a. The name of the protocol or other research activity;
 - b. A description of the research protocol/ activity, including the purpose of the research and the criteria for selecting particular records;
 - c. A brief description of the type of PHI that was disclosed;
 - d. The date or period of time during which disclosures occurred or may have occurred, including the date of the last such disclosure during the accounting period;
 - e. The name, address and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed;
 - f. A statement that the PHI of the patient may or may not have been disclosed for a particular research protocol/ activity.

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H. Documentation- All documentation required by this policy must be maintained for a period of six (6) years from the date of its creation or the date last in effect, whichever is later.

VI. ATTACHMENTS

Researcher Certification for Reviews Preparatory to Research, Researcher Certification for PHI of Decedents, HIPAA Waiver of Authorization Form, Subject Recruitment Authorization Form, Subject Recruitment: Physician's Documentation of Patient's Verbal Authorization Form, Research Sponsor Contract Privacy Provision

VII. REFERENCES

Standards for Privacy of Individually Identifiable Health Information, 45 CFR §164.501, §164.508, §164.512(i), §164.532(c), NY Civil Rights Law §79-1, NY Mental Hygiene Law §33.13, NY Mental Hygiene Law §33.16, NY Public Health Law §2782(1)

Date Reviewed	Revision Required (Circle One)		Responsible Staff Name and Title
	(Yes)	No	Shoshana Milstein /AVP, Compliance & Audit
9/2013	(Yes)	No	Rebecca Twersky
1/2014	(Yes)	No	Shoshana Milstein /AVP, Compliance & Audit
9/2016	Yes	(No)	Shoshana Milstein /AVP, Compliance & Audit
12/2016	Yes	(No)	Shoshana Milstein /AVP, Compliance & Audit



RESEARCHER CERTIFICATION FOR REVIEWS PREPARATORY TO RESEARCH

This form must be completed by any researcher seeking access to protected health information in preparation for research.

Researcher Name: _____
Last First MI

INFORMATION REQUESTED

Please describe in the space below the protected health information you would like to review.

I seek access to the above protected health information solely to:

- Prepare a research protocol
- Other purpose preparatory to research; specify _____

SPECIFIC REPRESENTATIONS

I will not remove any of the above information from SUNY Downstate's premises during the course of my review.

I affirm that access to the above protected health information is necessary for my review preparatory to research.

I understand that I may not record any protected health information in a way that may directly or indirectly be used to identify particular individuals in accordance with the policy on De-Identification of Information; however, I may maintain relevant databases reviewed for such preparatory purposes subject to the IRB's approval of the study if the Principal Investigator has determined to go forward with the study. The continued use and disclosure of the information maintained in such databases would require the appropriate authorization(s). If the study is not IRB approved, the databases/ identifying information must be deleted, properly disposed of and not retained for any purpose.

By signing below, I represent that all of the above statements are true.

Print Name of Researcher

Signature of Researcher

Date



RESEARCHER CERTIFICATION FOR PHI OF DECEDENTS

This form must be completed by any researcher seeking access to a decedent's protected health information for research on that decedent.

Researcher Name: _____
Last First MI

INFORMATION REQUESTED

Please describe in the space below the protected health information [including the name of the decedent(s)] you would like to review.

SPECIFIC REPRESENTATIONS

I seek access to the above protected health information solely for research on the protected health information of the decedent(s) named above. I understand that I may not request a decedent's medical history to obtain information about another living person such as a decedent's living relative.

I affirm that access to the above protected health information is necessary for my research purposes.

I agree to provide, at the Research Foundation's request, documentation of the death of the decedent(s) named above.

By signing below, I represent that all of the above statements are true.

Print Name of Researcher

Signature of Researcher

Date

Health Insurance Portability and Accountability Act (HIPAA) Waiver of Authorization Form

Principal Investigator: _____

IRB Number: _____

Project Title:

Under the federal privacy rule, 'HIPAA', research use or disclosure of an individual's identifiable health information (IIHI) requires the individual's authorization, unless the use or disclosure is determined by the IRB to qualify for a waiver.

Will your study involve looking at, using or disclosing IIHI? Yes No
If "No", then HIPAA does not apply. Check "No" and submit form to the IRB.
If "Yes" fill out the form below as indicated.

- I. List, in detail, the health information that is to be collected for the research activity, and, explain why this health information is the minimum necessary to meet the research objectives.
- II. Identify the source of the health information (e.g., medical record etc). Note that the source ('entity') must be able to account for disclosures made under this waiver.
- III. **The use or disclosure of IIHI for this research activity must involve no more than minimal risk to the privacy of individuals, based on the presence of the following 3 elements: (a and b below must be addressed)**
 - a. An adequate plan to protect the identifiers from improper use and disclosure. Describe this plan and indicate where IIHI will be stored, and who will have access (this list must be inclusive, i.e., sponsor, OHRP, FDA, data safety monitoring boards, research team as listed on the associated IRB application etc.).
 - 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 such retention is required by law.

IV. The research cannot practicably be carried out without the waiver.

Explain why:

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

Explain why:

My signature below assures that the IIHI obtained as above will not be reused or disclosed to any other person or entity, except as required by law, or for other research specifically approved by the IRB (and again, qualifying for a waiver of authorization)

Principal investigator signature at the end of this document signifies assurance of compliance with this requirement.

Principal Investigator

Date



SUBJECT RECRUITMENT AUTHORIZATION FORM

PLEASE NOTE: A summary of the basic information regarding the research study must be provided to the individual and must accompany this form.

Please read the information below carefully before signing this form. A representative of SUNY Downstate Medical Center is available to answer any questions regarding this authorization.

Patient Name: _____ MR#: _____

Address: _____

DOB: _____ Telephone#: _____ (Day) _____ (Eve)

I hereby authorize University Hospital of Brooklyn to disclose my information to the following physician/ research investigator at SUNY Downstate Medical Center for the purpose of contacting me regarding his/her research study:

Name: _____ Department: _____

Name of Research Study/ Protocol: _____

1. The following information will be disclosed: _____

2. New York State regulations [NY Public Health Law §2782(1)(b)] require a special authorization for release of information regarding mental health, any HIV- related condition (including HIV-related test, illness, AIDS or any information indicating potential exposure to HIV) or drug and alcohol abuse.

Do not authorize release of this information.

Authorize release of this information; specify the information to be released _____

I understand that this authorization will expire at the end of the subject recruitment phase of the research study, unless otherwise stated: Expiration Date: _____

By signing this authorization form, you authorize the use or disclosure of your protected health information as described above. This information may be re-disclosed if the recipient(s) described on this form is not required by law to protect the privacy of the information. If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from re-disclosing any HIV-related information without your authorization, unless permitted to do so under federal or state law. If you experience discrimination because of the release of disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 870-8624 or the New York City Commission of Human Rights at (212) 566-5493. These agencies are responsible for protecting your rights.

You have a right to refuse to sign this authorization. Your healthcare, the payment for your healthcare and your healthcare benefits will not be affected if you do not sign this form.

You have a right to receive a copy of this form after you sign it.

You have the right to revoke this authorization at any time, except to the extent that action has already been taken based upon your authorization. To revoke this authorization, please write to:

Print Name of Patient

Signature of Patient

Date



RESEARCH SUBJECT RECRUITMENT:

PHYSICIAN'S DOCUMENTATION OF PATIENT'S VERBAL AUTHORIZATION

Patient Name: _____ MR#: _____

Address: _____

DOB: _____ Telephone#: _____ (Day) _____ (Eve)

I hereby certify that I have discussed the following information with the patient identified above and that the patient has authorized me to disclose his/her information to the SUNY Downstate Medical Center physician/ principal investigator identified below for the purpose of research recruitment:

1. Physician/ Principal Investigator Name: _____

Department: _____

Research Study/ Protocol: _____

2. Information to be disclosed: _____

NOTE: This information may NOT include any information regarding mental health, any HIV- related condition (including HIV-related test, illness, AIDS or any information indicating potential exposure to HIV) or drug and alcohol abuse.

3. I informed the patient that s/he is not required to provide this authorization and that his/her healthcare, payment for healthcare and healthcare benefits will not be affected if authorization is not provided.

4. I further informed the patient that this authorization expires at the end of the subject recruitment phase of the research study, unless otherwise stated to me. I also notified the patient that s/he has a right to revoke the authorization if the information was not already disclosed to the physician/ principal investigator named above.

Print Name of Physician

Signature of Physician

Date

RESEARCH SPONSOR CONTRACT PRIVACY PROVISION

The following language may be used in a contract with a research sponsor to protect the confidentiality of individually identifiable health information provided to the sponsor in connection with the research. If the sponsor is not a covered entity under HIPAA, there may be no other way to restrict the sponsor's use or disclosure of the information. In some cases, the sponsor may want to be able to use and disclose such information and may object to any limiting language. Whatever language is inserted must be consistent with the description of the sponsor's uses and disclosures set forth in the research authorization signed by the subject. This language has been incorporated into a standard provision addressing the confidentiality of proprietary information in order to demonstrate how providers may choose to integrate this language into their existing research sponsor contracts or new contracts proposed by research sponsors.

Confidential Information.

- 1.1 In the performance of this Agreement, each party is likely to have contact with information of substantial value to the other, including, without limitation, information relating to identified patients and/or study subjects or to patients and/or study subjects whose identities may be ascertained by the exercise of reasonable effort through investigation or through use of other public or private databases; scientific techniques, designs, drawings, processes, inventions, developments, equipment, prototypes, sales and customer information; and business and financial information, relating to the business, products, practices or techniques (all of the foregoing hereinafter referred to as “Confidential Information”). Each party agrees, at all times, to regard and preserve as confidential such Confidential Information, and to refrain from publishing or disclosing any part of such Confidential Information or from using it, except as expressly otherwise provided pursuant to the terms and conditions of this Agreement. Sponsor agrees that it will keep and maintain in its custody and subject to its control any Hospital Confidential Information that it receives during the term of this Agreement, and agrees to return or surrender to Hospital, as the case may be, any Hospital Confidential Information upon termination of this Agreement.
- 1.2 Information received from either party to this Agreement shall not be deemed Confidential Information, and the receiving party shall have no obligation with respect to such information if: (i) such information, as of the effective date of this Agreement, is part of the public domain or becomes part of the public domain through no fault of the receiving party; (ii) such information was in possession of the receiving party on the effective date of this Agreement, as evidenced by prior written records kept in the ordinary course of the receiving party's business, and the information had not been wrongfully acquired, directly or indirectly, from the other party; (iii) such information is subsequently disclosed to the receiving party by a third party not in violation of any right of, or obligation to, the other party to this Agreement; (iv) such information is developed independently and without reference to the Confidential Information; or (v) such information is required by Hospital for medical treatment or patient counseling of study subjects.
- 1.3 In the event that either party receives a request to produce Confidential Information pursuant to an order of a court of competent jurisdiction or a facially valid administrative, Congressional, state or local legislative or other subpoena, or believes that such party is otherwise required by law to disclose Confidential Information, then the party from whom disclosure is sought shall promptly notify the other party to this Agreement prior to making such disclosure, and shall afford such party the opportunity to challenge or otherwise lawfully seek limits upon such disclosure of Confidential Information. The parties recognize a common goal of securing all individually identifiable health information and

according that information the highest possible degree of confidentiality and protection from disclosure and will use their best efforts in that regard.

1.4 The parties recognize a common goal of securing the integrity of all individually identifiable health information and according that information the highest possible degree of confidentiality and protection from disclosure. The parties will use their best efforts in that regard. Notwithstanding the foregoing provisions of this Section 1, or anything else in this Agreement to the contrary:

1.4.1 All individually identifiable health information (including information relating to patients and/or study subjects whose identities may be ascertained by the exercise of reasonable effort through investigation or through use of other public or private databases) shall be treated as confidential by the parties in accordance with all applicable federal, state and local laws, rules and regulations governing the confidentiality and privacy of individually identifiable health information, including, but without limitation, to the extent that each party is subject to it, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and any regulations and official guidance promulgated thereunder; and the parties agree to take such additional steps and/or to negotiate such amendments to this Agreement as may be required to ensure that the parties are and remain in compliance with the HIPAA regulations and official guidance;¹ and

1.4.2. the Sponsor, even if not a covered entity under HIPAA, recognizes that pursuant to this Agreement, Sponsor has the responsibility to protect all individually identifiable patient information consistent with the protections afforded to that information as Confidential Information set forth above; and only to use and disclose such information as necessary to discuss and analyze the results of the study, to ensure research integrity, to communicate with the Food and Drug Administration and other regulatory authorities, and otherwise as required by law or as permitted by authorizations or consents signed by study subjects or waiver of authorization granted by an IRB overseeing the study or that IRB’s affiliated Privacy Board (the “Permitted Activities”); and to restrict the use and disclosure of any individually identifiable patient information gained through the Permitted Activities to its workforce, contractors, subcontractors, study collaborators and agents who must have access to that information in order directly to support or facilitate the Permitted Activities; and to notify its workforce members, contractors, subcontractors, and agents of the requirements regarding protecting, using and disclosing such information in the fulfillment of their assigned duties, and to use any necessary means to bind those parties to these restrictions and requirements relating to individually identifiable patient information; and

1.4.3. the parties agree to cooperate with any reasonable requests from third party payors and/or government agencies with respect to the medical necessity of and reimbursement for medical services furnished to patients enrolled in the study, to the extent that those services are not reimbursed by Sponsor pursuant to this Agreement, and the parties shall cooperate with each other to narrow the scope of any such request from third party payors.

¹ Please note that some sponsors may object to any mention that they are subject to HIPAA; in that case, it may be acceptable to eliminate references to HIPAA in this paragraph, instead retaining references to “all applicable federal and state local laws.”