SUNY DOWNSTATE Medical Center

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;[i] 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.

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[i] 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."