Envision HEALTHCARE	Ethics & Compliance Department		
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HIPAA: USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH

SCOPE:

All Envision Healthcare teammates. For purposes of this policy, all references to "teammate" or "teammates" include temporary, part-time and full-time employees, independent contractors, clinicians, officers and directors.

PURPOSE:

Envision Healthcare Operating, Inc. and its subsidiaries and affiliates ("Envision" or "the Company") has adopted this Uses and Disclosures of Protected Health Information for Research policy to outline procedures for using and disclosing protected health information ("PHI") for research.

POLICY:

Research

A) In general, the Company will only use or disclose PHI created for the purposes of research, with the patient's authorization. However, the Company may use or disclose PHI collected for the purposes of research without patient authorization provided that:

(1) The Company obtains documentation that an alteration to or waiver, in whole or in part, of authorization has been approved by either an Institutional Review Board (IRB), or a privacy board.

(2) The Company obtains from the researcher representation that use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research; no PHI is to be removed from the covered entity by the researcher in the course of the review; and the PHI for which use or access sought is necessary for the research purposes.

(3) In the case of a deceased patient, the Company obtains from the researcher representation that the use or disclosure is sought solely for research on the PHI of the decedent, and representation that the PHI is necessary for the research purposes. The Company may request documentation of the death of the patient, from the researcher.

B) For a use or disclosure to be based on documentation of approval of a waiver, the documentation will include:

(1) A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved.

(2) A statement that the IRB or privacy board has determined that the alteration or waiver of authorization satisfies the appropriate criteria.

(3) A brief description of the PHI for which use or access has been determined to be necessary by the IRB or privacy board.

(4) A statement that the waiver of authorization has been reviewed and approved under either normal or expedited review procedures.

C) The Company will ensure that the following criteria is used in granting an approval for a waiver of authorization:

(1) The use or disclosure of PHI involves no more than minimal risk to the patients;

(2) The alteration or waiver will not adversely affect the privacy rights and the welfare of the patients;

(3) The research could not practicably be conducted without the alteration or waiver;

(4) The research could not practicably be conducted without access to and use of the PHI;

(5) The privacy risks to patients whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the patients, and the importance of the knowledge that may reasonably be expected to result from the research;

(6) There is an adequate plan to protect the identifiers from improper use and disclosure;

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

(8) 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 project, or for other research for which the use or disclosure of PHI would be permitted by this policy.

D) The Company will ensure that the following applies to an IRB or privacy board when reviewing and approving waivers associated with a research project:

(1) An IRB will follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

(2) A privacy board will review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who is not affiliated with the Company, not connected with any entity conducting or sponsoring the research, and any person affiliated with any such entities. The alteration or waiver of authorization will be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review;

(3) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the patients who are the subject of the PHI for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair.

POLICY REVIEW

The Ethics & Compliance Department will review and update this Policy, when necessary, in the normal course of its review of the Company's Ethics & Compliance Program.