CONNECTICUT VALLEY HOSPITAL
OPERATIONAL PROCEDURE MANUAL

SECTION II: ORGANIZATION-FOCUSED FUNCTIONS
POLICY 10: Management of Information
PROCEDURE 10.26: Use and Disclosure of Protected Health Information for Research

Purpose:

To inform all staff that Protected Health Information (PHI) can only be used for research purposes if certain criteria are met.

Definitions:

1. *Disclosure:* The release, transfer, provision of access to, or the divulging in any other manner of information outside the agency holding the information.

2. *Individually Identifiable Health Information:* Information that is a subset of health information, including demographic information collected from an individual, and that: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) 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 the provision of health care to an individual, and (3) which identifies the individual, or (4) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual. Note: Individually identifiable health information is to be treated as protected health information.

3. *Protected Health Information (PHI):* Individually identifiable information relating to past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for health care provided to an individual.

4. *Use:* With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

Procedure:

1. Connecticut Valley Hospital (CVH) may use or disclose PHI for research if at least one of the following criteria is met:

   a. CVH obtains a signed authorization (CVH-184) from the patient. *(See OP&P Procedure 10.19, Authorization for Use and Disclosure of Protected Health Information)*

b. CVH obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization has been approved by the Department of Mental Health and Addiction Services (DMHAS) Institutional Review Board (IRB).

c. CVH obtains from the researcher representation that:

   1. use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;

   2. no PHI is to be removed from CVH by the researcher in the course of the review; and

   3. the PHI for which use or access is sought is necessary for the research purposes.

d. CVH obtains from the researcher:

   1. representation that the use or disclosure is sought solely for research on the PHI of decedents;

   2. documentation, at the request of CVH, of the death of such individuals; and

   3. representation that the PHI for which use or disclosure is sought is necessary for the research purposes.

2. CVH may only permit use or disclosure based on documentation of approval of an alteration or waiver, which includes:

   a. a statement identifying:

      1. the IRB;

      2. the date on which the alteration or waiver of authorization was reviewed and approved under either normal or expedited review procedures; and

      3. a signature by the chair/designee of the IRB.

   b. a statement that the IRB has determined that the alteration to or waiver, in whole or in part, of authorization satisfies the following criteria:

      1. the use or disclosure of PHI involves no more than minimal risk to the individuals;

      2. the alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;

      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 individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, 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;

8. there are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted; and

c. a description of the PHI needed, including the use or access that has been determined to be necessary by the IRB.

3. The Hospital Research Committee ensures that the above documentation requirements are satisfied prior to permitting use and disclosure of PHI for research purposes.

Illustrations/Examples:

Example: A researcher requests identified data on individuals who have received services in the past but who are not currently available to sign a release form. Access may be granted if the IRB finds that such release of information is acceptable under the Health Insurance Portability and Accountability Act (HIPAA) privacy regulation and 45 CFR 46.