Research Uses and Disclosure of Protected Health Information Policy

Effective: 04/29/2014
Reviewed: 04/29/2014

Policy Statement

Palmetto Health may permit the use and disclosure of Protected Health Information for research with an individual Authorization, or without an individual Authorization under limited circumstances set forth in the Privacy Rule.

DEFINITIONS:

1. **Authorization:** The granting of rights to access, use or disclose protected health information.
2. **De-identified:** Information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. Palmetto Health may allow the use or disclose for research purposes, health information which has been de-identified in accordance with 45 CFR 164.502(d), and 164.514(a)-(c).
3. **Disclosure:** The release, transfer, provision of access to or divulging in any other manner of PHI outside Palmetto Health.
4. **Health Information:** Any information, whether oral or recorded in any form or medium that:
   1. Is created or received by a health care provider, health plan or public health authority, employer, life insurer, school or university, 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.
5. **Individually Identifiable Health Information:** Any information created, used or received by a health care provider that relates to:
1. The past, present, or future physical or mental health or condition of an individual.
2. The provision of health care to an individual, or
3. The past, present, or future payment for the provision of health care to an individual with respect to which there is a reasonable basis to believe the information can be used to identify the individual. The collection of individually-identifiable health information for research constitutes human subjects research.

6. Institutional Review Board (IRB): A board designated by Palmetto Health to review research involving humans as subjects, to approve initiation of and conduct periodic review of such research.

7. Limited Data Set: PHI from which all direct identifiers, such as name, have been removed but may contain some indirect identifiers.

8. Principal Investigator (PI): An individual having the background and training in scientific and administrative oversight necessary to conduct and manage research activities.

9. Privacy Rule (Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule): National standards that protect individuals’ medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.

10. Protected health information (PHI): All individually identifiable health information created, received, transmitted or maintained in any form or medium. It is information relating to the past, present or future physical health, mental health or condition of an individual. PHI either identifies or could be used to identify the individual.

11. Research: A systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

12. Use: The sharing, employing, applying, utilizing, examining or analyzing individually identifiable health information within Palmetto Health.

POLICY SPECIFICATIONS:

1. Palmetto Health may permit the use or disclosure of PHI for research under the following circumstances:
   1.1. For preparatory to research activities.
   1.2. For research on a decedent’s PHI.
   1.3. With IRB approval of an alteration or waiver of the individual Authorization.
   1.4. With an individual Authorization.
   1.5. As a de-identified data set.
   1.6. As a limited-data set.
   1.7. If informed consent of the individual or a waiver to such consent was obtained prior to April 14, 2003.
2. Preparatory to Research Activities
   2.1. Palmetto Health may permit the use and disclosure of PHI to develop a research protocol or for similar purposes preparatory to research (e.g., to determine whether the institution has information about prospective research participants that would meet the eligibility criteria for enrollment in a research study). Principal investigators should be aware that this exception does not permit the continued use or disclosure of the PHI once the principal investigator has determined to go forward with the study. For example, using PHI to contact eligible subjects for recruitment purposes would not be permitted under this exception.

   2.1.1. In order to permit a use or disclosure of PHI under this exception, Palmetto Health must obtain representations from the Principal Investigator that:
      2.1.1.1. The use or disclosure is sought solely to prepare a research protocol or for similar purposes preparatory to research;
      2.1.1.2. No researcher will remove any PHI from the institution’s premises in the course of the review; and,
      2.1.1.3. The PHI for which use or access is sought is necessary for the research purposes.

3. Research on the PHI of a Decedent:
   3.1. Palmetto Health may permit the use and disclosure of the PHI of a decedent for research purposes. In order to permit such a use or disclosure, Palmetto Health must obtain representations from the Principal Investigator that:
      3.1.1. The use or disclosure is sought solely for research on the PHI of a decedent (e.g., principal investigators may not request a decedent’s medical history to obtain health information about a decedent’s living relative) and that the information for which use or disclosure is sought is necessary for the research purposes.
      3.1.2. The Principal Investigator must provide, at Palmetto Health’s request, documentation of the death of any individuals about whom information is sought.

4. De-identified Information:
   4.1. Palmetto Health may allow the use and disclosure de-identified information for research purposes. The Creating De-Identified Information PGR must be followed.

5. Limited Data Set:
   5.1. Palmetto Health may allow the use and disclosure of a limited data set for research purposes when de-identified information is not sufficient and full disclosure of PHI is not necessary. The Creating and Using a Limited Data Set PGR must be followed.
      5.2. A limited data set cannot be sold without individual authorization.

6. Individual Authorization:
   6.1. Palmetto Health may allow the use and disclosure of PHI pursuant to a completed and signed authorization form. Permissible uses and disclosures are limited to those described in the authorization, even though those permissible uses and disclosures may
be more limited than what the Palmetto Health’s Notice of Privacy Practices describes. The Authorization for Use and Disclosures of PHI PGR must be followed.

6.2. The Psychotherapy Notes: Using and Disclosing PGR must be followed if applicable.

7. Institutional Review Board Approval of Alteration or Waiver of Authorization

7.1. Palmetto Health may allow the use and disclosure of PHI for research purposes if the IRB grants an alteration or waiver of the authorization requirement. If the IRB grants an alteration – that is, if it modifies or waives only some elements of the authorization – the IRB must condition the use and/or disclosure of any PHI for research purposes on compliance with any authorization requirements not waived and as modified. For example, if the IRB grants an alteration of authorization to allow a principal investigator to obtain PHI to recruit potential research participants, the principal investigator would still have to obtain authorizations from the subjects to use or disclose PHI for the study itself.

8. Informed Consent or Waiver of Informed Consent Obtained Prior to April 14, 2003

8.1. Palmetto Health may approve the use or disclosure of PHI for a specific research project provided that one of the three following requirements are met:

8.1.1. Express Legal Permission For Use and Disclosure of PHI.

8.1.1.1. If the principal investigator has obtained, prior to April 14, 2003, express legal permission from the individual that specifically authorizes a use or disclosure of PHI for purposes of the research project, Palmetto Health may permit such use or disclosure for purposes of that project. However, any restrictions on the use and disclosure of health information provided in such express legal permission must be honored.

8.1.2. General Informed Consent.

8.1.2.1. If the principal investigator has obtained, prior to April 14, 2003, the individual’s informed consent to participate in a specific research project, Palmetto Health may permit a use or disclosure for purposes of that project even though the informed consent does not specifically authorize the use or disclosure of PHI for purposes of the research project. However, any restrictions on the use and disclosure of health information provided in such informed consent must be honored.

8.1.3. Waiver of Informed Consent.

8.1.3.1. If the principal investigator has obtained, prior to April 14, 2003, an IRB waiver of the informed consent requirement (in accordance with the Common Rule) for a specific research project, Palmetto Health may permit a use or disclosure of the individual’s PHI for purposes of that project. However, if the principal investigator obtains an individual subject’s informed consent at any time after April 14, 2003, the principal investigator will also be required to obtain the individual’s authorization at that time.
REFERENCES
45 CFR 164
Corporate Compliance Policy and PGRs:
   HIPAA Privacy Policy
   Accounting for Disclosures PGR
   Authorization for Use and Disclosures of PHI PGR
   Creating and Using a Limited Data Set PGR
   Creating De-Identified Information PGR
   Psychotherapy Notes: Using and Disclosing PGR

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04/29/2014