DEFINITIONS:

1. Authorization: The granting of rights to access, use or disclose PHI.
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. (refer to Creating De-Identified Information PGR)
3. Disclosure: The release, transfer, provision of access to or divulging in any other manner of PHI outside Palmetto Health.
4. 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.
5. Limited Data Set: PHI from which all direct identifiers, such as name, have been removed but may contain some indirect identifiers. (refer to Creating and Using a Limited Data Set PGR)
6. Minimum Necessary: The least amount of PHI necessary to satisfy the request or to complete the task. (refer to Minimum Necessary PGR)
7. Principal Investigator: An individual having the background and training in scientific and administrative oversight necessary to conduct and manage research activities.
8. 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.

9. **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.

10. **Psychotherapy Note:** Notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a counseling session. Psychotherapy notes do not include medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date. (refer to Psychotherapy Notes: Using and Disclosing PGR)

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.

13. **Workforce Member:** employees, independent contractors, volunteers, students, trainees, medical residents, fellows and other persons whose conduct in the performance of work for Palmetto Health is under the control of the organization, regardless of whether the individuals are receiving compensation from Palmetto Health. Legal counsel has the ultimate authority to determine whether someone is acting as a workforce member of Palmetto Health.

**RESPONSIBLE POSITIONS (TITLE):**

Principal Investigator  
Study Staff

**EQUIPMENT NEEDED:**

Internet access with eIRB privileges  
FORM: Request for Use and Disclosure of Protected Health Information, Preparatory to Research  
FORM: Request for Use and Disclosure of Protected Health Information, Decedent Research  
TEMPLATE: Authorization for Use and Disclosure of Protected Health Information for Research

**PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS**

1. **PURPOSE**
   1.1. This guidance describes how to use or disclosure of PHI for research.  
   1.2. The procedure begins when a principal investigator submits a request for use or disclosure of PHI for research.  
   1.3. The procedure ends when the use and/or disclosure, and accounting of disclosures are
completed.

2. **PROCEDURE**

2.1. For preparatory to research activities or research on the PHI of a decedent, complete the “FORM: Request for Use and Disclosure of Protected Health Information, Preparatory to Research,” or “FORM: Request for Use and Disclosure of Protected Health Information, Decedent Research”. Submit the form to Research-Assist@palmettohealth.org.

2.2. For all other requests for research use and disclosure of PHI complete the Privacy section of the eIRB Application SmartForm.

2.2.1. The “TEMPLATE Research Authorization” may be used as a stand-alone authorization or added to the Informed Consent for Research to create a compound authorization.

2.3. Use or disclosure of PHI for research may begin when written approval of the request is received.

2.4. The *Accounting for Disclosure PGR* must be followed.

2.5. **Note:** A waiver of individual authorization is not a waiver of the requirements of informed consent for the project or of any other consent required by Palmetto Health policies.

**REFERENCES**

45 CRF Part 164

Corporate Compliance Policy and PGRs:
- HIPAA Privacy Policy
- Accounting for Disclosures PRG
- 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