DEFINITIONS:

1. **Case Report**: Retrospective analysis of one, two, or three clinical cases. If more than three cases are involved, the Investigator usually starts asking specific research questions which lead to a formal systematic collection of data and a prospectively designed research study. Thus with four or more cases, the activity must be reviewed by Palmetto Health’s Institutional Review Board (IRB) per Human Research Protection Program Policy.

2. **HIPAA**: Health Insurance Portability and Accountability Act as amended

3. **Investigator**: An individual having the background and training in scientific and administrative oversight to conduct and manage research activities.

4. **Research Staff**: Individuals who assist in a research project overseen by an Investigator.

RESPONSIBLE POSITIONS (TITLE):

- Investigators and/or Research Staff

EQUIPMENT NEEDED:

- N/A

PROCEDURE STEPS, GUIDELINES, OR REFERENCE

1. **PURPOSE**: Although a case report does not require IRB review and is typically a medical/educational activity, there are HIPAA implications. This procedure sets forth the steps necessary to conduct compliant case reports.
2. **PROCEDURE**

2.1. Investigators who wish to publish case report data with HIPAA identifiers will need to obtain from the patient a signed Palmetto Health HIPAA authorization. (A current copy of the authorization may be obtained from Palmetto Health’s Privacy Officer.) This signed authorization should be maintained in the Investigator’s records.

2.2. Investigators who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission and publication of the information do not need to obtain a signed privacy authorization. Refer to Corporate Compliance’s *Creating De-Identified Information PGR* to obtain a list of HIPAA identifiers.

2.3. If the Investigator strips all HIPAA identifiers, but the information associated with the subject of the article includes a “unique characteristic” which would make it identifiable to the subject, or the Investigator has actual knowledge that the information about the subject could be used alone or in combination with other information to identify the subject, the Investigator must contact Palmetto Health’s Privacy Officer to discuss the required steps to take prior to publication.

2.4. The publication and presentation of case reports must follow [Publication of Research Results Policy](#).

2.5. Investigators should inform Research Compliance Office if a journal editor does not accept Palmetto Health’s determination that producing a case report does not constitute research. The specifics of such a situation will be discussed with the Palmetto Health IRB and Corporate Compliance Office, along with the Institutional Official and/or designee.

**REFERENCES**

Corporate Compliance: Creating De-Identified Information PGR

[Human Research Protection Program Policy](#)

[Publication of Research Results Policy](#)