



POLICY FOR DETERMINING IF RESEARCH IS SUBJECT TO OR EXEMPT FROM THE PRIVACY RULE (HIPAA)

04/18/2008

The Privacy Rule sets forth policies to protect all individually identifiable health information (protected health information, PHI) that is held or transmitted by a covered entity. Health 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, is not individually identifiable health information. Therefore, such de-identified health information is not subject to (is exempt from) the Privacy Rule.

The purpose of this document is to define the procedure for determining if a research activity is subject to or exempt from the Privacy Rule.

45CFR164 sets forth policies for the protection of subject privacy (HIPAA Privacy Rule). 45CFR164 section 514 (b) defines the requirements for de-identification of protected health information and allows for exemption from IRB review.

The Privacy Rule applies to all research activities that involve creating, accessing, storing, or disclosing individually identifiable health information (PHI), about living or deceased persons, related to human tissue samples, chart reviews and/or stored in databases or repositories. Research not meeting this criterion is not subject to the Privacy Rule.

For research that does meet that criterion, a covered entity may determine that health information is not individually identifiable health information if it is de-identified by one of two methods:

1. De-identification Certified by Statistician or Qualified Individual

A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable accomplishes **both** of the following:

- determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by anticipated recipient to identify an individual who is a subject of the information; and
- documents the methods and results of the analysis that justify such determination;

2. De-identification by Removal of 18 Identifiers

- a. **All** of the following identifiers of the individual or of relatives, employers, or household members of the individual must have been

removed to qualify for exemption from the privacy rule (HIPAA):

- Names;
 - All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
 - (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000. According to the August 2002 Final Modifications to the Privacy Rule and utilizing the 2000 Census data, there are 17 restricted three-digit ZIP codes that correspond to populations of 20,000 or fewer persons and must be changed to 000 to be de-identified: 036, 059, 063, 102, 203, 556, 692, 790, 821, 823, 830, 831, 878, 879, 884, 890, and 893.
 - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
 - Telephone numbers;
 - Fax numbers;
 - Electronic mail addresses;
 - Social security numbers;
 - Medical record numbers;
 - Health plan beneficiary numbers;
 - Account numbers;
 - Certificate/license numbers;
 - Vehicle identifiers and serial numbers, including license plate numbers;
 - Device identifiers and serial numbers;
 - Web Universal Resource Locators (URLs);
 - Internet Protocol (IP) address numbers;
 - Biometric identifiers, including finger and voice prints;
 - Full face photographic images and any comparable images; and
 - Any other unique identifying number, characteristic, or code; and
- b. The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

REFERENCES

45CFR164.514(b)

ATTACHMENTS

Checklist for Determining If an Activity Qualifies for Exemption under the Privacy Rule

Checklist for Determining If an Activity Qualifies for Exemption Under the Privacy Rule

Principal Investigator: _____

Project Title: _____

The Privacy Rule protects all “individually identifiable health information” [or protected health information (PHI)] held or transmitted by a covered entity. Health 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, is not individually identifiable health information. Therefore, such de-identified health information is not covered by the Privacy Rule and does not require IRB review.

Regulation	Checklist Questions	Yes	No
45 CFR 164.514(a)	<p>1. Does the research activity involve creating, accessing, storing, or disclosing individually identifiable health information (PHI), about living or deceased persons, related to human tissue samples, chart reviews and/or stored in databases or repositories?</p> <p style="margin-left: 40px;">If yes, continue. A covered entity may determine that health information is not individually identifiable health information if it is de-identified by one of two methods described in the categories below. Continue with question 2.</p> <p style="margin-left: 40px;">If no, STOP. Privacy Rule does not apply.</p>		
45 CFR 164.514(b) (1)(i)	<p>2. Has a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable (a Statistician or Qualified Individual*) determined that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by anticipated recipient to identify an individual who is a subject of the information?</p> <p style="margin-left: 40px;">If yes, continue with question 3.</p> <p style="margin-left: 40px;">If no, STOP. The activity does not Qualify for Exemption under the Privacy Rule.</p> <p style="margin-left: 40px;">*De-identification by this method requires prior approval from Tina R. Tyson, J.D., Chief Compliance Officer, DUMC School of Medicine. Please attach documentation of approval.</p>		
45 CFR 164.514(b) (1)(ii)	<p>3. Has the person from the above question documented the methods and results of the analysis that justify such a determination?</p> <p style="margin-left: 40px;">If yes, STOP. The activity does not involve individually identifiable health information and, therefore, qualifies for exemption under the Privacy Rule.</p> <p style="margin-left: 40px;">If no, continue with question 4.</p>		

45 CFR 164.514(b) (2)(i)	<p>4. Have ALL the following identifiers of the individual or of the relatives, employers, or household members of the individual been removed?</p> <ul style="list-style-type: none"> ○ Names; ○ All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: <ul style="list-style-type: none"> (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000. According to the August 2002 Final Modifications to the Privacy Rule and utilizing the 2000 Census data, there are 17 restricted three-digit ZIP codes that correspond to populations of 20,000 or fewer persons and must be changed to 000 to be de-identified: 036, 059, 063, 102, 203, 556, 692, 790, 821, 823, 830, 831, 878, 879, 884, 890, and 893. ○ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older ○ Telephone numbers; ○ Fax numbers; ○ Electronic mail addresses; ○ Social security numbers; ○ Medical record numbers; ○ Health plan beneficiary numbers; ○ Account numbers; ○ Certificate/license numbers; ○ Vehicle identifiers and serial numbers, including license plate numbers; ○ Device identifiers and serial numbers; ○ Web Universal Resource Locators (URLs); ○ Internet Protocol (IP) address numbers; ○ Biometric identifiers, including finger and voice prints; ○ Full face photographic images and any comparable images; and ○ Any other unique identifying number, characteristic, or code; <p style="text-align: center;">If yes, continue with question 5. If no, <u>STOP</u>. The activity does not Qualify for Exemption under the Privacy Rule.</p>		
45 CFR 164.514(b)(2)(ii)	<p>5. Do you (or does the Covered Entity) have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information?</p> <p style="text-align: center;">If yes, the activity does not involve individually identifiable health information and, therefore, qualifies for exemption under the Privacy Rule. If no, the activity does not qualify for exemption under the Privacy Rule.</p>		

Signature of Principal Investigator: _____

Printed Name: _____

Date: _____