

HIPAA Procedure 5032 PR.1

Determining Whether "Human Subject Research" Activity Involves Use/Disclosure Of "Protected Health Information"

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Purpose

To determine which "human subject research" activities involve Protected Health Information (PHI) and are therefore subject to the federal HIPAA Privacy Rule (HIPAA). See Yale University Policy [5032](#) - Statement of Policy on Use and Disclosure of Protected Health Information For Research Purposes for additional information on the federal HIPAA requirements related to research.

Background

Research activities that involve PHI require a specific research authorization signed by each research subject, a waiver of authorization for the study approved by an IRB or Privacy Board, or assurances from the researcher that the PHI is needed as part of a review preparatory to research or for research on the PHI of decedents who have been deceased for 50 years or less. If no PHI will be created, used, acquired or disclosed as part of a human subject research activity, no HIPAA research authorization, waiver of authorization, or assurance is required for the activity. *Projects initiated prior to April 14, 2003, in which informed consent was waived by an IRB do not require a research authorization. For studies that require informed consent, those subjects who have executed an informed consent to participate in the project prior to April 14, 2003, do not have to sign a research authorization unless the subject is re-consented after April 14, 2003.*

Analysis

1. Will the study data be "individually identifiable" as defined in Attachment A, at any point in the activity or project?

Yes _____ No _____

If "Yes", continue with the analysis.

If "No", the data are not PHI and this activity is not subject to HIPAA.

NOTE: No attempt may be made to identify the study subjects. If subjects become identifiable, the Principal Investigator should notify the Chair of the approving IRB and the Privacy Officer at all sites responsible for the study data, so that appropriate remedial action may be taken.

2. Will the individually identifiable data in the study relate 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?

Yes _____ No _____

If "Yes", continue with the analysis.

If "No", the data are not PHI and this activity is not subject to HIPAA.

3. Does the protocol call for the individually identifiable data to be created or received by any person or entity that is either a health care provider or a workforce member of any part of Yale University's Health Care Component (School of Medicine (Excluding the School of Public Health, the Animal Resource Center, and the basic science departments: the Departments of Cell Biology, Cellular and Molecular Physiology, Comparative Medicine, History of Medicine, Immunobiology, Microbial Pathogenesis, Molecular Biophysics & Biochemistry, Neurobiology, Pharmacology, and WM Keck Biotechnology Resources Laboratory), School of Nursing, Yale Health, Department of Psychology clinics)?

Yes

No

_____ If "Yes", the data are PHI and this activity is subject to HIPAA.

_____ If "No", the data are not PHI and this activity is not subject to HIPAA.

5032 Exhibit A: Individually Identifiable Data

Data are "individually identifiable" if any of the following 18 types of identifiers are contained in the information or if anyone accessing the information has actual knowledge that the information could be used – alone or in combination with other information – to identify any individual who is the subject of the information. Note that this does not prohibit coding records so that they may later be re-identified, so long as the code does not contain information about the subject of the information (for example, the code may not be a derivative of the individual's Social Security Number) and is not used or disclosed for any other purpose, and so long as the re-linking mechanism (e.g., the subject log or coding algorithm) is not disclosed to any persons or organizations outside of Yale University. [An additional option of engaging a qualified expert to render a formal written opinion to the Yale University Privacy Officer is discussed in Yale University Policy [5039](#) - Use and Disclosure of De-Identified Information and of Limited Data Sets.]

1. Names
2. All geographic subdivisions smaller than a State, including:
 - street address
 - city
 - county
 - precinct
 - zip codes 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.
3. Telephone numbers
4. Fax numbers
5. E-mail addresses
6. Social Security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. All elements of dates (except year) for dates related to an individual, including:
 - birth date
 - admission date
 - discharge date
 - date of death
 - 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

11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying numbers, characteristics, or codes

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