



Quality Assurance and Quality Control

The high quality of data within FITBIR is crucial for ensuring its usefulness and reliability for research. Therefore, the NIH has implemented a multi-tiered quality control procedure for data contributed to FITBIR.

Validation of Data Made Available by FITBIR

NIH is not a HIPAA covered entity (there is no electronic medical billing related to intramural/Clinical Center study participants). FITBIR, being part of NIH, is also not a HIPAA covered entity. However, the HIPAA Limited Dataset definition will be used as the basis for this certification. Specifically, FITBIR contributors will ensure that the following direct identifiers of the research subject or of relatives, employers, or household members associated with the research subject are removed prior to upload as per the FITBIR Data Sharing Policy:

1. Names;
2. Postal address information, other than town or city and state or 3 digit zip code;
3. Telephone numbers;
4. Fax numbers;
5. Email addresses;
6. Social Security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate or license numbers;
11. Vehicle identifiers and license plate numbers;
12. Device identifiers and serial numbers;
13. URLs associated with an individual;
14. IP addresses;
15. Biometric identifiers; and
16. Full-face photographs and any comparable images.

Any potential discrepancies to this privacy rule (e.g., genomics data or images that could be transformed) will be documented and approved/denied by the FITBIR Data Access and Quality Committee (DAQC).

Background Info

The Privacy Rule: What Information is Protected?

Protected Health Information. The Privacy Rule protects all "*individually identifiable health information*" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information (PHI)."¹²

"Individually identifiable health information" is information, including demographic data, that relates to:

- the individual's past, present or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual,

and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.¹³ Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

The Privacy Rule excludes from protected health information employment records that a covered entity maintains in its capacity as an employer and education and certain other records subject to, or defined in, the Family Educational Rights and Privacy Act, 20 U.S.C. §1232g.

De-Identified Health Information. There are no restrictions on the use or disclosure of de-identified health information.¹⁴ De-identified health information neither identifies nor provides a reasonable basis to identify an individual. There are two ways to de-identify information; either: (1) a formal determination by a qualified statistician; or (2) the removal of specified identifiers of the individual and of the individual's relatives, household members, and employers is required, and is adequate only if the covered entity has no actual knowledge that the remaining information could be used to identify the individual.¹⁵

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>



To Whom Does the Privacy Rule Apply and Whom Will It Affect?

Key Points:

- The Privacy Rule applies only to covered entities. Many organizations that use, collect, access, and disclose individually identifiable health information will not be covered entities, and thus, will not have to comply with the Privacy Rule.
- The Privacy Rule does not apply to research; it applies to covered entities, which researchers may or may not be. The Rule may affect researchers because it may affect their access to information, but it does not regulate them or research, per se.
- To gain access for research purposes to PHI created or maintained by covered entities, the researcher may have to provide supporting documentation on which the covered entity may rely in meeting the requirements, conditions, and limitations of the Privacy Rule.

In conclusion, NIH is not a HIPAA covered entity (there is no electronic medical billing related to intramural/Clinical Center study participants). FITBIR, being part of NIH, is also not a HIPAA covered entity.

http://privacyruleandresearch.nih.gov/pr_06.asp