



Assessment Tool 2: Am I Using Protected Health Information? (PHI)

Complete this checklist to identify the type of identifiers that you propose to collect, use or disclose from a medical record. This will help the IRB determine if HIPAA regulations apply, and assess the appropriate level of risk and review for your study.

Project Title: _____

| Identifiable Information | Direct Identifiers | | Indirect Identifiers | | No (check if not collected) |
|---|----------------------------------|-----------------------------|----------------------------------|-----------------------------|--------------------------------|
| | Used/Collected (check if yes) | Disclosed (check if yes) | Used/Collected (check if yes) | Disclosed (check if yes) | |
| 1. Name of research subject or relatives, employers, or household members. | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 2. Geographic subdivisions smaller than a State (street address, city, county, precinct, zipcode & geocodes ¹ (Note: for the records to be considered de-identified only the first three digits of the zip code can be used) | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ¹ The first three digits of the zip code may be used as long as the population in that region is greater than 20,000. If the geographic unit is less than 20,000 only state may be used. | | | | | |
| 3. Dates (except year) directly related to an individual (date of birth/death, dates of admission/discharge etc.) AND ages over 89 and all elements of dates indicating such ages. (Note: this information can be aggregated into a single category of age 90 or older.) | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Telephone numbers | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 5. Fax Numbers | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 6. Electronic mail addresses | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 7. Social security numbers | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 8. Medical record numbers | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 9. Health plan beneficiary numbers | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 10. Account numbers | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 11. Certificate/ license numbers | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 12. Vehicle identifiers and serial numbers, including license plate numbers | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |



Assessment Tool 2: Am I Using Protected Health Information? (PHI)

| | | | | | |
|---|--------------------------|--------------------------|--|--|--------------------------|
| 13. Implanted device identifiers and serial numbers | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 14. Web Universal Resource Locators (URLs) | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 15. Internet Protocol (IP) address numbers. | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 16. Biometric identifiers, including finger and voice prints or any audio recordings. | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 17. Full face photographic images and any comparable image, including video recordings. | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |
| 18. Any other unique identifying number, characteristic, or code. | <input type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> |

After completing this tool, see below to determine which route of approval you should follow:

- ✓ If you check “yes” to these categories (1, 4-18), it is Protected Health Information*. Data is **identifiable** and must adhere to HIPAA regulations. A consent **and** HIPAA authorization must be included with the IRB submission OR the PI must request a **Waiver or alteration of Authorization**.
- OR
- ✓ If you only check “yes” to categories 2 & 3 (see blue shaded area), data is considered to be a **Limited Data Set (LDS)**. An LDS includes certain dates and geographic data. Covered entities and researchers who wish to disclose or obtain an LDS must enter into a **Data Use Agreement** and include this with the IRB submission.
- OR
- ✓ If you check “no” to all 18 categories below, data is fully de-identified. You are NOT using PHI and are not required to follow HIPAA Privacy Rule regulations. A code may be maintained to re-identify the PHI but it **cannot** be derived from or related to the information about the subject (e.g., patient initials or digits of their social security number, or be disclosed by the covered entity).

Continue below to complete the Certification of De-Identification for your records. Please submit this form to appropriate records administrator.

Certification of De-Identification:

Assurance Statement: The information on this form is accurate and the identifiers listed in this document will not be recorded as part of this research study. I agree to the Privacy Rule's requirements on re-identification.

Principal Investigator's Name:

Date:

Principal Investigator's Signature: _____

- My department is in the covered entity.
- My department is NOT in the covered entity, but data will be de-identified before it is given to me.
- My department is NOT in the covered entity, but I will de-identify the data on behalf of the covered entity after signing a Business Associate Agreement.