

HIPAA Research Roadmap*

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| <p>Are you intending to collect data on any of the 18 personal health identifiers?</p> <ol style="list-style-type: none"> 1. Names 2. Street address, city, county, 5-digit zip code 3. Months and dates (years are OK) and ages >89 (unless all persons over 89 years are aggregated into a single category) 4. Telephone numbers 5. Fax numbers 6. E-mail addresses 7. Social security number 8. Medical record number 9. Health plan beneficiary number 10. Account number 11. Certificate/license number 12. Vehicle identification number (VIN) and/or license plate number 13. Device identifiers and serial numbers 14. URLs (Uniform Resource Locators) 15. Internet protocol address number 16. Biometric identifiers, such as finger and voice prints 17. Full face photographic images or any comparable images 18. Any other unique identifying number, characteristic, or code such as patient initials | <p>No →</p> | <p>HIPAA does not apply.</p> |
| <p>Yes ↓</p> | | |
| <p>Will the Protected Health Information (PHI) be completely de-identified, based on one of these criteria?</p> <ol style="list-style-type: none"> a. The data collection forms and database will be stripped of all 18 identifiers, and the Master Link irrevocably destroyed shortly after subject enrollment. b. A statistician can verify that there is less than a “very small” risk that an individual’s identity can be detected. | <p>Yes →</p> | <p>No Authorization or Waiver is necessary.</p> |
| <p>No ↓</p> | | |
| <p>Can you limit your collection of personal health identifiers to just dates, city/state/zip, and/or “other unique identifier” (#18 above)? (defined as a “limited data set” in HIPAA-speak)</p> | <p>Yes →</p> | <p>Provide a Data Use Agreement. No Authorization or Waiver is necessary.</p> |
| <p>No ↓</p> | | |
| <p>Is obtaining patient Authorization “impracticable”, as determined by the IRB? (protocol may qualify as “HIPAA minimum risk”).</p> | <p>Yes →</p> | <p>Request Waiver in protocol, but disclosures must be tracked.</p> |
| <p>No ↓</p> | | |
| <p>Is data collection “preparatory to research” in order to determine how many potential research subjects meet study recruitment criteria?</p> | <p>Yes →</p> | <p>No Authorization necessary.</p> |
| <p>No ↓</p> | | |
| <p>Research subject will need to sign Authorization – the Authorization should be separate from the informed consent form</p> | | |

* Note: HIPAA is a complex law, and its research application is still subject to interpretation. This Roadmap is subject to revision as the interpretation of the law evolves. March 10, 2003