

**HIPAA Privacy Rule Requirements Effective April 14, 2003 for
Databases Used for Research Purposes**

The purpose of this decision tool is to provide guidance in applying the requirements of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 C.F.R. Parts 160 and 164) to appropriate existing databases containing “protected health information” (PHI), to the creation of new databases that will contain PHI, and to the research use of databases containing PHI.

General Instructions:

1. Failure to determine whether the HIPAA Privacy Rule applies to your database or research use of a database may result in the interruption of your research beginning on **April 14, 2003**.

2. This decision-making process should be applied to **EACH** database and to **EACH** research project that uses PHI contained in a database. Specific HIPAA Privacy Rule requirements and documentation as well as necessary IRB action will depend on the characteristics of each database or each research use of a database.

3. Please answer each question in the order presented to identify guidance appropriate to your database or research use of your database. If you deviate from the ordered progression of questions, you may end up unnecessarily applying HIPAA Privacy Rule requirements to research use of your database or research project.

4. If the research purpose of your use of a database changes, the HIPAA requirements and resulting IRB actions will likely also change.

5. If your database contains information from only a single study, it does **NOT** need to be registered, regardless of whether it was created before or after April 14, 2003.

Do the HIPAA Privacy Rule requirements apply to research use of my database?

1. Does the database contain information involving the health of individually identifiable people, including indirect identifiers such as medical record or other uniquely identifying numbers?

YES NO

2. Is the database used in any connection with research involving human subjects, including but not limited to nonprotocol-specific research activities such as contact information for future research recruitment?

YES NO

NOTE: If the answer to either question #1 or #2 is NO, then HIPAA Privacy Rule requirements **DO NOT APPLY** to the use of the database for research purposes. It is unnecessary for you to continue through this decision tool; research use of your database requires no HIPAA Privacy Rule documentation, registration, or action by an IRB until your answers to questions #1 and #2 change for this particular database.

If the answers to questions #1 and #2 are YES, then HIPAA Privacy Rule requirements **MAY APPLY** to the database. Please continue and answer the following two questions, which will help you determine whether or not the requirements apply.

3. Is the database populated with information obtained from the provision of health care services?

YES

NO

4. Will any information from research participation contained in the database be included in the official medical records of the people who are identified with the information? For example, will the results of research interventions such as drug administration, blood tests, x-rays, or other imaging be entered into the medical records of study participants?

YES

NO

If you answered NO to BOTH questions #3 and #4, HIPAA Privacy Rule requirements DO NOT APPLY to use of the database for research purposes until one of your answers to questions #3 and #4 changes for this particular database.

If you answered YES to either question #3 or #4, HIPAA Privacy Rule requirements DO APPLY to the use for research purposes of any database (existing or under development) that has the above characteristics. As a result, you must register your database by completing and filing the “[Database Registration Form and Preparatory to Research Certification for Database Custodian](#)” form. You must also apply the [HIPAA Privacy Rule requirements](#) to each use for research purposes of PHI in your database.

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