

## Database Decision Tool

The purpose of this decision tool is to provide guidance in applying the requirements of the HIPPA Privacy Rule 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:**

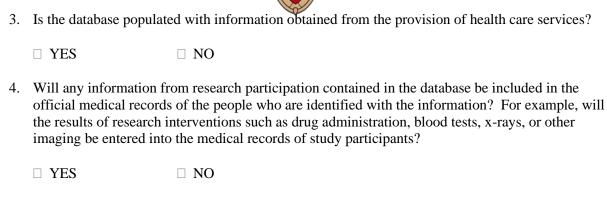
- Failure to determine whether the HIPAA Privacy Rule applies to your database or research use of a database may result in the interruption of your research.
- This decision-making process should be applied to <u>each</u> database and to <u>each</u> research project
  that uses PHI contained in a database. 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.
- 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.
- If the research purpose of your use of a database changes, the HIPAA requirements and resulting IRB actions will likely also change.
- If your database contains information from only a single study, it does <u>NOT</u> need to be registered, regardless of when it was created.

## 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 way with research involving human subjects (even if used for other non-research purposes, e.g., quality improvement), including but not limited to non-protocol specific research activities such as contact information for future research recruitment?	
	□ YES	□ NO

<u>Note</u>: If the answer to <u>either</u> question #1 or #2 is NO, then HIPAA Privacy Rule requirements <u>DO NOT</u> 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.



If you answered NO to BOTH questions #3 and #4, HIPAA Privacy Rule requirements <u>DO NOT</u> 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 <u>either</u> question #3 or #4, HIPAA Privacy Rule requirements <u>DO</u> 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 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.