PURPOSE

To provide guidance about permissible uses and disclosures of Protected Health Information (PHI) for research purposes (see 45 CFR § 164.512(i)).

REVIEW/REVISIONS

- 02/2016

REFERENCES AND RELATED FORMS

- HIPAA Privacy Program Guidance (Definitions)
- Human Subjects Protection Program: http://rgw.arizona.edu/compliance/human-subjects-protection-program

GENERAL INFORMATION ABOUT HIPAA AND RESEARCH

HIPAA permits the access, disclosure and use of Protected Health Information (PHI) from a HIPAA Covered Entity for research purposes in the following six methods:

1. The signed authorization of the patient whose individually identifiable PHI is sought;
2. Waiver by an IRB or a Privacy Board of all or part of the authorization requirement for use of individually identifiable PHI;
3. A Data Use Agreement for research use of a Limited Data Set (see definition below);
4. Review of PHI solely in preparation for research, without collecting the PHI for research use;
5. Complete de-identification of the PHI; or
6. Use of PHI solely of decedents.

SIX METHODS FOR USING OR DISCLOSING PHI FOR RESEARCH

1. **Research Use or Disclosure of PHI with Authorization (may include any and all individual identifiers)**
    - As a general rule, a researcher must obtain a signed Authorization from all participants in research prior to the internal use or external disclosure of PHI for any research related purpose that is not otherwise permitted or required under HIPAA.
    - The IRB, HIPAA Privacy Program, and/or Covered Entity will provide an Authorization template that complies with HIPAA requirements.
    - Special note: An Authorization is always required for access, disclosure or use of psychotherapy notes.

2. Research Use or Disclosure of PHI with Waiver of Authorization by IRB (may include any and all individual identifiers approved by the IRB in its waiver)
    - In some circumstances, Authorizations for research use of PHI may be waived by the IRB, provided the following three criteria are satisfied and documented (generally in addition to satisfaction of waiver of informed consent requirements pursuant to 45 CFR 46.116):
        - The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on HIPAA-prescribed criteria;
        - The research could not practicably be conducted without the waiver; and
        - The research could not practicably be conducted without access to and use of the PHI.
    - A request for Waiver of Authorization must be completed by the researcher and submitted to the IRB for prior review and approval.
    - Uses or Disclosures of PHI made pursuant to a Waiver are subject to the HIPAA Minimum Necessary rules.
    - Since a researcher cannot practicably obtain a potential research participant's authorization for review of PHI in advance of contacting the potential participant, the IRB may issue a limited waiver of authorization permitting specified access and use of PHI solely for prescreening and recruitment contact pursuant to an approved protocol.
    - Physicians and other health care professionals who have a direct treatment relationship with an individual may review that individual's PHI for eligibility with respect to a research protocol and may initiate a discussion with the individual about potential participation as a research subject in a protocol relevant to the treatment relationship. This scenario does not require an Authorization or a Waiver of Authorization.
    - Individuals responding to an advertisement or otherwise initiating contact and indicating interest in participating in a research study may be given an explanation of the study (including, but not limited to, the name of the principal investigator and description of the study) without Authorization or Waiver of Authorization; however, either their Authorization or a Waiver of Authorization is required to review their PHI in health care records to determine potential eligibility.

3. Research Use of a Limited Data Set
    - A researcher may use or disclose a Limited Data Set for research without an Authorization or IRB Waiver of Authorization. A limited data set as defined in HIPAA is described below. Although even a Limited Data Set is nearly de-

identified, this limited amount of PHI consisting of certain geographic data and dates may be adequate for a broader array of research studies than completely De-Identified data.

- A Limited Data Set contains PHI that is nearly de-identified. A Limited Data Set may NOT include any of the direct identifiers listed under the HIPAA definition of De-Identified health information (see HIPAA Privacy Program Form Q) EXCEPT the following:
    - State, county, city, town, census track, precinct, zip code or any other geocodes above the level that would identify an individual household; and/or
    - All elements of dates directly related to an individual, including birth date, admission date, discharge date, dates of health care procedures or other services, and date of death.
- The Limited Data Set must exclude ALL OTHER direct identifiers listed in HIPAA Privacy Program Form Q: (http://rgw.arizona.edu/sites/researchgateway/files/q_is_it_phi.pdf).
- A Limited Data Set may be used or disclosed only if there is a Data Use Agreement between the entity providing the data and the recipient of the limited data set. A researcher should contact the HIPAA Privacy Program if he/she needs or receives a Data Use Agreement for a Limited Data Set.
- A researcher may find the need to access full PHI in order to abstract from that a Limited Data Set for research use. Because this abstraction activity requires access to PHI, a researcher may ONLY engage in this abstraction activity under the following circumstances:
    - The researcher must have an IRB waiver of authorization; or
    - In addition to a Data Use Agreement, the researcher must enter into a Business Associate Agreement with the Covered Entity to create the Limited Data Set on the covered entity's behalf for the researcher's use. IMPORTANT: Contact the HIPAA Privacy Program for assistance in this situation.

4. Access to PHI solely for Preparation for Research

- Researchers may access PHI in the records of Covered Entities without an Authorization or IRB Waiver of Authorization for the purposes of development of a research protocol or assessment of feasibility of a research protocol, provided that the researcher documents to the satisfaction of the Covered Entity's PHI data custodian (e.g. the medical records manager) that all the following criteria are

satisfied (typically via an attestation form provided by the Covered Entity to be signed by the individual researcher):

- The use or disclosure of PHI is solely to prepare or assess feasibility of a research protocol;
- The researcher shall not record individually identifiable PHI or remove PHI from the records reviewed (for example, researcher may review identifiable PHI but may only record aggregate data or individual data that does not include any individual identifiers);
- The PHI sought is necessary for the purposes of the research; and
- The researcher shall not contact or recruit patients under this provision.

5. Use or Disclosure of Completely "De-Identified" Health Information

- The HIPAA definition of completely De-Identified PHI is not the same as what many researchers have been accustomed to consider "anonymized" data. The completely De-Identified form of data defined in HIPAA may not be adequate for many research studies. An advantage is that it presents no risk of privacy violation and therefore requires relatively little documentation for research access or use and is not subject to any restrictions on downstream use and disclosure.
- Individual health information that conforms to the HIPAA definition of "de-identified" is exempt from HIPAA and may be used or disclosed for research purposes without an Authorization or Waiver of Authorization or Data Use Agreement.

6. Use and Disclosure of Decedent's Individually Identifiable PHI Without Authorization

- Researchers may use and disclose a decedent's individually identifiable PHI for research without an Authorization or IRB Waiver, provided that the researcher documents that all the following criteria are satisfied:
  - The use will be solely for research on the PHI of a decedent; and
  - The researcher has documentation of the death of the individual about whom information is being sought, and
  - The PHI sought is necessary for the purposes of the research.
- The researcher will provide documentation to the data custodian that all of the above criteria are satisfied in accordance with the data management registration process.
- Uses or Disclosures of a decedent's PHI for research purposes are subject to the HIPAA Minimum Necessary rules.