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07. Special Considerations

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7.1* Does this study involve human tissue or biological specimens (use, collection, or secondary analysis) (e.g. blood, urine, bone marrow, skin, etc.)? [Require Section 18]

● Yes ○ No Clear

7.1.1* Will genetic analysis be performed on any specimens acquired in conjunction with this study? [Require Section 20]

○ Yes ○ No Clear

7.2* Does this study involve the secondary analysis of a pre-existing data set, including data associated with any specimens identified in response to question 7.1? [Require Section 24]

○ Yes ○ No Clear

Studies that are limited to retrospective review of medical records ARE considered secondary data analysis. Consultation of medical record information in conjunction with a study involving interaction/intervention (e.g., screening for eligibility) is not necessarily considered secondary data analysis. In either case, a request for full or partial waiver of informed consent and HIPAA authorization may be required.

7.3* Will the research involve the access, collection, use, maintenance, or disclosure of protected health information (PHI)? PHI is:

- **information about a subject's past, present, or future physical or mental health, the provision of healthcare to a subject, or payment for the provision of healthcare to a subject; AND**
- **maintained by a HIPAA-covered entity (e.g. healthcare provider, healthcare plan, or healthcare clearinghouse).**

[Require Section 25]

○ Yes ● No Clear

Protected Health Information (PHI) includes one or more HIPAA identifiers.

Most data generated from clinical records is regulated by Health Insurance Portability and Accountability Act (HIPAA). HIPAA generally covers both data provided directly by a HIPAA "covered entity" and data provided by a central data broker and protected by contractual agreements.

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