



Editing: HUM00010807

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10. Informed Consent - Secondary Use of Existing Data/Records/Specimens

Completion of this section is required based on the response provided to questions 1-1.1, 5.2 and 5.3.

Full waiver is very common for secondary-use studies

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10.3* What type of informed consent will be obtained from subjects for the use of their data, records and/or specimens?

Select all that apply:

- Request for waiver of informed consent/parental permission/legally authorized representative consent
- Pre-existing consent(s) covers this activity
- Re-consent/assent subjects for use of existing data/records/specimens for a new research purpose

10.3.1* Describe terms and conditions of original consent process.

Was the prior consent for research, clinical other purposes? Was future use explicitly addressed? Are there limitations on the type of future research allowed? Was permission for future use required, or a choice by the subject?

Activates 10.3.1 and 10.3.2 below. This applies to data/biospecimens obtained from some repositories, such as UMMS Central Biorepository. This answer often pairs with "Yes, always" to HIPAA authorization question 25-1.3.

10.3.2 Upload any documents related to consent, assent, permission, and or debriefing documents, including oral scripts here.

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10.3.3* Describe the plan to assent, consent, or re-consent the subject or the subject's legally authorized representative.

Activates 10.3.3 and section 10-1.