eRESEARCH | REGULATORY MANAGEMENT SAND

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05. Research Design

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5.1* Is there a stand-alone scientific protocol document and/or research plan associated with this application?

○ Yes ● No Clear

NO activates section 05-1. YES activates a document uploader.

5.2* Will the involvement of ANY subjects in this study be limited to analysis of their existing data or specimens?

● Yes ○ No Clear

Always YES for a secondary-use-only study

Other than any potential informed consent process, there will be no DIRECT interaction/intervention with these subjects. Involvement for these subjects is limited to analysis of subject data in existing databases, data sets, medical records, and/or specimens from banks or repositories.

5.2.1* How many subjects are represented in the data or specimens to be analyzed?

99999 *(do not enter commas, dots, or special characters)*

Enter a HIGH estimate for the TOTAL number of records you will access

5.3* Will the study involve recruitment and/or participation of subjects in order to produce new data (e.g., surveys, interaction, intervention)? *[Require sections 8-1 and 11-3]*

○ Yes ● No Clear

Always NO for a secondary-use-only study

5.4* List the inclusion and exclusion criteria for this study population and/or data set. (If covered in attached protocol, indicate section)

Describe the subject population - diagnosis/diagnoses and/or healthy subjects, adults and/or children, time range for when data/specimens were or will be generated, &c.

5.5 Identify any racial, ethnic, or gender group(s) that will be specifically excluded from participation in this research study and provide a compelling justification for such exclusion:

5.6* Indicate the age range (in years) of the subject population in this study.

Minimum Age: 0

Maximum Age: 999 If no upper limit, enter "999"

The IRB is using this information to evaluate the type of consent form that may be required for this research. For some studies (e.g., pediatric studies), more detailed age ranges (e.g., 6-18 months) may be spelled out in a protocol or research design document, but in this instance, enter ages in whole numbers only, rounding to the nearest year.

5.8* **The primary risk of conducting research with secondary data or specimens is a breach of confidentiality or privacy, which may cause psychological, social/reputation, legal, or financial harm. Indicate any risks to subjects other than these risks from a breach of confidentiality or privacy. If there are none, answer "none."**

none

This question in the Secondary Research Uses pathway replaces Section 06 in the interaction/ intervention research pathway.

Additional Help

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