05. Research Design

Hide Help

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

○ Yes ● No Clear

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

● Yes ○ No Clear

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?

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

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

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

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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: 18

Maximum Age: 99 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."

It is now system-possible to show a MIOM sec use study

Additional Help

5.9* What is the level of risk of harm to the subjects, resulting from this secondary use research?

	Risk Level	Description
○	No more than minimal risk	A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination. (Note: The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.) Refer to the Risk Grid for more information.
●	Minor increase over minimal risk	While this risk category may be used to classify research involving adult subject populations, it must be considered in the evaluation of risk in research involving children as defined in 45 CFR 46 sections 404-407*** Risks are more severe than those defined as “No more than minimal risk” and less severe than those described as “Moderate” on the Risk Grid.
○	Moderate risk	Refer to the Risk Grid for more information.
○	High risk	Requires scrutiny in regards to the likelihood of direct benefits, and whether or not benefits clearly outweigh risks. Refer to the Risk Grid for more information.

Clear

Risk Grid
more than minimal risk to subjects. Study teams reduce the risk of breach of confidentiality by adhering to standard data security guidelines.