

IRBIS changes, effective 6:00 PM, April 8, 2021

IRBIS System Update:

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Progress Report Update to 1.D.

When you are submitting a renewal and select a Renewal Action of 1.C, 1.D, or 1.E, your response to Progress Report 1.D will be auto-filled with '0' and will be locked to indicate that no subjects will be enrolled in the upcoming review period.

1. Renewal action requested by Principal Investigator (choose only one): *

Study has always involved only analysis of data or specimens; there has never been any direct interaction or contact with subjects.

A) Continue study as approved.

Study involves (or involved) direct interaction/intervention/contact with subjects.

B) Continue study as approved, including enrollment of new subjects.

C) Enrollment of new subjects closed; research-related interaction/intervention and long-term review of medical records or registry (as described in questionnaires, surveys or interview (e.g., review of medical/health records)) will be completed.

D) Enrollment of new subjects closed; subjects have completed and continued review of medical records or registry (as described in questionnaires, surveys or interview (e.g., review of medical/health records)).

E) All research-related interaction/intervention and long-term review of medical records or registry (as described in questionnaires, surveys or interview (e.g., review of medical/health records)) for this study is in data analysis. Once data analysis for this study is complete, the study will be closed.

1. Number of Subjects involved through direct contact or contact with subjects:

A. Total projected number as approved by IRB:
 (Prior Response)

B. Total number of subjects included/enrolled to date (do not include subjects who have been disenrolled or withdrawn):
 (Prior Response)

C. Number of subjects included/enrolled since last renewal:
 (Prior Response)

D. Number to be included/enrolled in upcoming year *
 (Prior Response)

E. Since initial approval, have any subjects been enrolled in the study?

Update to A.8 Data Analysis section

The two versions of the Data Analysis section have been merged so that all Full Form and Multi-Site applications have the same set of questions. All studies will now have version 2 which consists of four questions.

For studies that had completed responses for version 1, they have been moved to the new section as indicated below. These studies will need to provide responses for the remaining two questions.

Version 1:

A.8.1. > Describe the analytical methods to be used (qualitative or quantitative) => A.8.1

A.8.2. > Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or an explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies) => A.8.3

Version 2:

A.8.1. > Summarize the statistical analysis strategy for each specific aim.

A.8.2. > If this is a pilot study, please describe the future study and say how its study design, aims, sample size, and methods differ from the pilot study you are proposing.

A.8.3. > Provide a compelling justification for the proposed sample size in terms of the likelihood of achieving each aim.

A.8.4. > Summarize the plans for data management.