HUMAN SUBJECTS IN ASSIST

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When completing an NIH grant application in the online platform ASSIST, if you check ‘Yes’ for Human Subjects in the NIH Grant application in the section “RESEARCH & RELATED Other Project Information” then you will have to submit Human Subjects Study Plans for each distinct data collection effort in your project (e.g., if one part of the same population under study is qualitative and one part is quantitative, that’s two study plans).

Here are official NIH instructions:
<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm>

Here are my instructions to give to the pilot grantees who are required to submit the information. The sections referred to in the step-by-step instructions are from the UC Berkeley IRB protocol form. So while you do not need to have an approved protocol prior to submitting and only would seek it upon receiving a fundable score, the IRB template will come in handy for now and later.

If there is no Human Subjects give the reason (e.g., public depersonalized data).

Section 1: The title is the title of your grant, or if you have more than one data collection plan, e.g. one for parents and one for teachers, then the first you could give a title of ‘Parents’ and the second ‘Teachers’, or whatever you find most descriptive.

1.2 No -> 1.3 NA

1.4a = yes

 b-c: if all are yes then it is clinical. If so there are more issues, such as registering the trial with NIH, that go beyond the scope of this document.

1.5 NA

2.1 These are the MESH terms : Search here for relevant terms:
[https://meshb-prev.nlm.nih.gov/search](https://meshb-prev.nlm.nih.gov/searchk)

2.2 Age Limits. Section 5a from protocol

2.3 Section 5a

2.3.a See <https://grants.nih.gov/policy/inclusion/lifespan.htm>. A document similar to and replacing the former ‘Children’ document in NIH applications. A short paragraph describing justification for age range, particular exclusions.

2.4 Women & Minorities document in NIH applications.

2.5 Sections 6a, 6b, 7a, 7b

2.6 (not yet recruiting, actively recruiting, active data collection, completed, suspended, terminated)

2.7 include some kind of timeline information - could be table, chart, or just bullets
[Note: unless your FOA calls for it specifically in the Research Strategy, you can refer reviewers to here for your timeline and save yourself some real estate.]

2.8 Date of enrollment of first participant

2.9 The enrollment/inclusion table. Save the application (save and release lock) before you open this section. Then go back into the page, and then you can edit this subsection.

It has 6 self-explanatory question to begin. Then you enter the numbers for the proposed enrollment form. See table at the end of this document to use as a guide – I recommend filling it in so that it’s easier to do in ASSIST.

[Note: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#Inclusion>
-"All studies must enter planned enrollment counts unless your proposed study will use only an existing dataset or resource. Planned enrollment generally means that individuals will be recruited into the study and/or that individuals have already been recruited and continue to be part of the study."

And

-" You must enter cumulative enrollment counts if your proposed study will use an existing dataset or resource. "]

3.1 The human subjects document in NIH applications, with paragraphs on

 a. Characteristics of the Study Population.
 b. Sources of Material.
 c. Recruitment and Consent Procedures.
 d. Potential Risks.
 e. Adequacy of Procedures for Protecting against Risks.
 f. Potential Benefits of the Proposed Research to the Subjects and Others.
 g. Importance of the Knowledge to be Gained.

3.2 Probably ‘no’

3.3 Another document. Section 13 a-g. Optional if not Clinical Trials. However, may be warranted if there are significant risks to the study population.

3.4 No (not necessary for research that is not Clinical Trials.

3.5 Optional if not Clinical Trials.

4.1a, b Don't fill out the rest - it's for clinical research only

And that's it!

The table below is an excel file so you can copy/paste it into an excel document and the formulae should work. Or you can edit it here (PCs: right click -> worksheet object -> edit.)

