

Question and Answer Session Transcript

*“Opportunities for Collaborative Research at the NIH Clinical Center”
Pre-Application Webinar, November 5, 2013*

How detailed will the X02 budget need to be?

A budget is not requested with the X02 pre-application, but the research strategy should describe the amount of work proposed and provide information about the kinds of resources needed and personnel that will be involved.

Do we need to include all the biosketches in the X02?

Yes.

Do we need to include the clinical protocol and animal study details in the X02?

As noted in the instructions, the X02 pre-application should indicate “No” for human subjects. Therefore, human subject related materials are not required. Thus, there is no need to submit sections 5,6,7,8 and 9 for the X02. Nor are the planned enrollment tables required, but they are required for the full application (U01). But while the human subject attachments are not required for the X02, the FOA does require that if the proposed research involves human subjects or patients, then the research strategy must address the work to be done and provide information about the number of patients, types of tests, etc. This information is essential in determining whether or not the research can be accommodated by the Clinical Center resources.

Do we need an attachment for data or resource sharing plan for the X02?

Yes, a resource sharing plan is required.

If I submitted an application in the first cycle, should I plan to submit an X02 pre-application? In other words, can I just use the letters of support I received in the last cycle for this application? And carrying that further, can we copy and paste the old budget from the last cycle, including the Clinical Center's budget in the application?

It would not be appropriate to simply use last year's letters of support. While the X02 pre-application is not required, it is strongly recommended. There may be changes in your project since the last submission, especially if you revise the plan to address any weaknesses noted by reviewers. Those changes may affect the ability of the Clinical Center to support the work or the intramural scientist to be involved. The X02 is shorter and should not be onerous for anyone who has already submitted a U01 application. The X02 should focus on what are you going to do, what resources are you going to use at the Clinical Center, how many patients, how many tests, etc., and these details will allow staff at the ICs and the Clinical Center to determine whether or not your project can be supported before you write a U01 application.

Does the X02 require a detailed statistical section with justification for sample size? Does the X02 require detailed statistical section on analysis, analysis plan?

The answer to both questions is no. Although the attachments are not required for the X02, information about the sample size should be provided in the research strategy section of the application.

How much detail on the clinical cohorts are required as part of the X02?

The research strategy section of the X02 is limited to six pages. This section should be written to address the X02-specific review criteria as described in the FOA. .

The X02 collaboration plan and the X02 research strategies request similar information about the details of the collaboration. Should the information be given in both places?

The two documents are separate entities, but the key points should be addressed in both.

How much detail on the actual research proposal should be included in the X02 research strategy, that is, background, approach, et cetera?

Applicants will need to provide a sufficient amount of information to answer the questions that are part of the review criteria. One major purpose of the X02 is to determine whether it's possible to do the project at the CC with intramural resources. So, for example, if someone wanted to study neonatal delivery, that would not be possible at the Clinical Center because we don't have a neonatal unit.

Does the Clinical Center, in this program, include the potential for collaboration with NIDA's intramural research program in Baltimore?

The work could not be done exclusively at NIDA's intramural research program in Baltimore. Some project work must occur at the Clinical Center. If that requirement is met, you are not excluded from also doing work at NIDA's site in Baltimore, so long as one of the participating institutes is willing to support the work.

Under collaborations, can the extramural clinics collaboration with the NIH Clinical Center and contribute clinical cohorts within an integrated study result?

Yes, we encourage that.

Can there be two external centers, one clinical, one non-clinical, maybe basic science sequencing centers integrated into the study?

Yes.

Are these announcements seeking to fund predominantly observational studies with translational targets or clinical trials? Could both types of applications be considered?

Yes, both types of applications will be considered.

I am an NIH intramural investigator, and my institute is not participating in this FOA. Can I still apply as a partner on this program?

Absolutely. To apply, you will need to find an IC that would be willing to support your project.

In the case of an application with multiple PIs, should the contact PI be the extramural or the intramural PI?

As noted in the FOA, the extramural PI should be the contact PI.

I am an extramural investigator. How do I identify an intramural PI to partner with?

Go to the website <http://www.cc.nih.gov/translational-research-resources/research.html> To identify investigators interested in your area of research, you can search the **Database of NIH Intramural Research Reports**, the **Intramural Principal Investigator Directory**, and the **Search the Studies** website. When contact information is not available on the above sites, you will find contact information for NIH investigators on the **NIH Directory**. You may also contact the research contact at the appropriate institute as listed in the FOA if you need additional suggestions.

Is the X02 pre-application required as a pre-condition for submitting a U01 application at a later time?

No, the X02 pre-application is not required. However, individuals interested in applying to the U01 funding opportunity are strongly encouraged to apply to the X02 pre-application, in order to reduce the burden on applicants should their research plan not be feasible to be conducted utilizing the resources of the NIH Clinical Center, or not relevant to the research missions of any of the participating NIH institutes. In addition, the submission of an X02 pre-application will facilitate the provision of letters of support from the Clinical Center Director and the relevant institute, which are required for a complete U01 application. Information provided in the X02 pre-application will also help to identify the relevant NIH Clinical Center costs, and thus facilitate preparation of the budget section for the U01 application.

Are there examples of the U01 or X02s available?

At this time, no, because the awards have not yet been issued. Once the awards have been made, one can, through freedom of information, request to see the applications. Examples of the X02s will not be available.

Question: Do you have GLP (Good Laboratory Practice) capabilities to do clinical and pre-clinical work on new drugs, toxicology, et cetera?

A section of the NIH Clinical Center (CC) Pharmacy does operate a GMP/GLP facility (Pharmaceutical Development Section-PDS) that is capable of reformulating and repackaging drugs from raw materials. This service includes formulating drugs and matching placebos, sterile injections, and other products into suitable dosage forms as required by the protocol.

PDS is able to confirm that raw materials are suitable for human use and develops the manufacturing and testing procedures needed to produce a deliverable drug to be able to study its pharmacokinetics and pharmacodynamics for phase one trials. Preclinical work is primarily limited to formulation, assay development, trial runs of mock infusions, and stability

monitoring. PDS provides much of the data needed for the Chemistry, Manufacturing and Controls (CMC) section of the IND for submission to the FDA. Generally PDS is not involved in toxicology issues.