Instructions and Helpful Hints for October 15, 2012 Resubmission

Application Process:

ALL FY 2012 and FY 2013 applications must be submitted electronically through grants.gov (http://www.grants.gov1). Applicants can apply electronically by visiting the Web site www.grants.gov and following instructions under ‘‘Apply for Grants". Users of grants.gov will be able to download a copy of the application package, complete it offline, and then upload and submit the application via the grants.gov Web site. We strongly encourage using the ‘‘Tips’’ posted on www.grants.gov under the announcement number when preparing your submission. Applicants should also take the time to read the Request for Applications (RFA–FD-11-001) that was published in the Federal Register on August 6, 2010 as well as the publication in the NIH Guide.

Before Applying:
In order to apply electronically, applicants must have a Data Universal Number System (DUNS) number, and register in (1) the Central Contractor Registry (CCR) database, (2) in eRA Commons4, and (3) in grants.gov. A valid Taxpayer Identification Number (TIN) or Employer Identification Number (EIN) is necessary for CCR registration. Applicants should allow a minimum of five (5) days to complete the CCR registration.

Principle Investigators (PIs) also will need to make sure they are registered with the eRA Commons (Creating PI Account). A registration process with Grants.gov and eRA Commons is necessary before submission and applicants are highly encouraged to start the process at least 4 weeks prior to the grant submission date.

Award Amounts and Dates:
Phase 1 studies are eligible for up to $200,000 per year for up to 3 years. Phase 2 and 3 studies are eligible for up to $400,000 per year for up to 4 years. Please note that the dollar limitation will apply to total costs (direct plus indirect). Budgets for each year of requested support may not exceed the $200,000 or $400,000 total cost limit, whichever is applicable.

For **FY 2012**, the application receipt date is **February 2, 2011** and for **FY 2013**, the application receipt date is **February 1, 2012**. Please note that there is only ONE receipt date for FY 2012 and FY 2013 for new and resubmitted applications. However, resubmissions and applications that were submitted previously will be allowed to resubmit **October 14, 2011** and **October 15, 2012**. ***Resubmissions will also be accepted in the February receipt dates in both Fiscal years.***

Notification regarding the results of the review is anticipated by September 2011 for FY 2012 and by September 2012 for FY 2013. The earliest expected start date for the FY 2012 and FY 2013 awards will be November 1, 2011 and November 1, 2012, respectively.

Helpful Hints

The following hints will facilitate the review of your application by the Office of Orphan Products Development (OOPD). In the past, the most frequent errors noted on applications by OOPD include omission of the IND or IDE number in grant title, omission of the submission date of the study protocol to the IND or IDE, and lack of documentation of the prevalence of the disease or condition. Please see RFA posted on NIH Guide5 or Federal Register notice6 for more.

1. Face Page

a. Title of Project

Action Items:

i. In the title, please be sure to include ALL the following information: (1) the phase of the study; (2) the name of the drug/device; (3) the name of the disease/condition to be studied; (4) the IND/IDE number; and (5) the date the protocol you are requesting funding for was submitted to FDA review division. Please limit your character length to 81 characters to avoid errors.

ii. If this application is a resubmission, please indicate the previously assigned grant application number on the face page to avoid errors.

iii. Please include the IND/IDE number and date it was submitted to the review division in the title block.

b. IND/IDE

The study protocol proposed in the grant application **must** be under an active IND or IDE (not on clinical hold) to qualify the application for scientific and technical review. INDs or IDEs should be submitted to the review division **at least thirty days** before the grant application receipt date as specified in the announcement for this program posted in the Federal Register. Studies of approved products to evaluate new orphan indications are acceptable; however, these must also be conducted under an IND or IDE to support a change in labeling. Protocols that would otherwise be eligible for an exemption from the IND/IDE regulations must be conducted under an active IND/IDE to be eligible for funding under this FDA grant program.

Action Items:

i. The number assigned to the IND/IDE that includes the proposed study should appear on the face page of the application with the title of the project.

ii. The date the subject protocol was submitted to FDA for the IND/IDE review should also be provided in the title of the project.

c. DUNS Number

In order to apply electronically, applicants must have a DUNS number and register at the Central Contractor Registration database7.

Action Items:

i. To obtain a DUNS number, call 1-866-705-5711.

ii. Be certain to identify yourself as a Federal grant applicant when you call.

iii. Please place this number on the face page of the application.

2. Research Plan

Background and Significance OOPD provides grants for clinical studies that will either result in or substantially contribute to market approval of products used inthe prevention, diagnosis and/or treatment of rare diseases.

Action Items:

i. Please include in the "Background and Significance" section an explanation of how the proposed study will either help gain product approval or provide essential data needed for product development.

ii. The prevalence, not incidence, of the population to be served by the product must be fewer than 200,000 individuals in the United States. Please include, in the "Background and Significance" section, a detailed explanation supplemented by authoritative references in support of the prevalence figure. If you have received Orphan Drug status, please include your designation number in this section. If you have applied to OOPD for Orphan Drug designation, please include the designation number and date of submission.

3. Consent Forms

Action Item:

Consent forms, assent forms, and any other information given to a subject, should be sent with the grant application, even if such a form is in a draft version. They should be included in the appendix.

4. Product Availability

Evidence that the product to be studied is available to the applicant in the form and quantity needed for the clinical trial must be included in the application in the Background section.

Action Item:

Please provide such evidence in the Background section of the application. A current letter from the supplier as an appendix (referenced in the Background Section) is acceptable.

5. SBIR/STTR

This information applies to Small Business Innovation Research and Small Business Technology Transfer grants. These questions do not apply to your OPD grant application. Therefore, any reference or request for information pertaining to an SBIR/STTR grant can be deleted/omitted/marked "not applicable".

6. Budget

The NIH Modular Budget program does not apply to the OPD grant program.

7. Page Limits

Please note that these page limitations do differ from NIH page limits.

The following are the maximum page limits for the following sections:

Introduction - maximum 1 page

Research Plan - maximum 25 pages

Biographical Sketch - maximum 4 pages

Project Summary/Abstract – maximum 1 page

Project Narrative – maximum 1 page

Page limits are based on single-spaced pages, with 0.5 inch margins, in 11 pt. font or larger.

Applications may not be accepted for review and may be returned for the following reasons:

1) The applicant organization is ineligible.
2) The application is received after the specified receipt date.
3) The application is incomplete.
4) The application is illegible.
5) The application is not responsive to the Request for Applications (RFA).
6) The material presented in the application is insufficient to permit an adequate review.
7) The dollar amount requested in the application exceeds the recommended threshold stated in the RFA.

8. Resubmission Details

If this is a resubmission, revision or renewal, the prior grant number is mandatory.

i. Responses to prior critiques (for a "resubmission") should be in the PHS 398 Research Plan component, upload #1 ("Introduction to Application").

Section 2.7 "Resubmission" of the SF424 (R&R) Application Guide provides details for the applicants.

See:http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerB.doc8

ii. Please note that acceptance of a resubmission application automatically withdraws the prior version, since two versions of the same application cannot be pending simultaneously. Introduction to Resubmission Application: The resubmission must include a brief Introduction (1-3 pages depending on the mechanism) that summarizes the substantial additions, deletions, and changes. The Introduction must also include responses to the criticisms and issues raised in the Summary Statement. Use Item 2.1, Introduction to Application, of the PHS 398 Research Plan component to provide this information.

9. Character Restrictions

On the SF424 R&R form the following character restrictions apply:

i. Applicant information: Name and PI contact information, position, and titles – must be < 40 characters

ii. Applicant information: Street address – must be < 50 characters

iii. Descriptive Title – must be < 81 characters

iv. Person to be contacted and Authorized Representative name and position/title – must be < 30 characters each

10. Attachments

i. Attachments must be in PDF only

ii. All attachments must not be password protected

iii. There is a limit of 10 attachments total

iv. If pages are greater than 11 x 11 inches or less than 8.5 x 8.5 inches software should change the page size from actual to 8.5 x 11 inches.

v. It is recommended to give the appendices a name that is meaningful and not rely on sequential order.

vi. See Section 5.5 of the Research Plan Component http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerB.doc9 in the Application Guide describes the page limitations and appendix guidance in detail.

11. Other Information:

Please be aware that the following documentation must be received by the FDA before an award is made:

a. Federal Wide AssuranceFederal Wide Assurance (FWA or assurance) obtained from Office for Human Research Protections (OHRP) (http://www.hhs.gov/ohrp10/) for the IRB of record for all performance sites must be on file with the FDA grants management office before an award to fund the study will be made. No awardee or performance site institution may spend funds on human subject research or enroll subjects without the approved and applicable assurance(s) on file with OHRP.

b. IRB of Record

Any institution receiving Federal funds must have an institutional review board (IRB) of record even if that institution is overseeing research conducted at other performance sites. An awardee institution must have its own IRB of record. The IRB of record may be an IRB already being used by one of the "performance sites," but it must specifically be registered as the IRB of record with the OHRP.

c. IND/IDE

The study protocol proposed in the grant application must be under an active IND or IDE (not on clinical hold) to qualify the application for scientific and technical review. Confirmation will be required that the IND/IDE is active (not on hold) and in regulatory compliance.

Only medical foods that do not need pre-market approval and medical devices that are classified as non-significant risk (NSR) are free from these IND/IDE requirements. Applicants studying an NSR device should provide a letter in the application from the FDA Center for Devices and Radiologic Health indicating the device is an NSR device.

d. ClinicalTrials.gov

After an award is made, you must register your trial with ClinicalTrials.gov. See RFA for more information.