Orphan Products Development (OPD) Clinical Trials Grants:

Application Instructions and Helpful Hints for 2019 Receipt Date

Application Due Date:

The application submission deadline for the RFA is **June 25, 2019** by 11:59 PM Eastern Time. The earliest submission date is April 25, 2019. Please note that there is only **ONE** receipt date for Fiscal Year 2020 which occurs in June. Please see the Request for Application (RFA) for details.

A **letter of intent** is by **May 25, 2019**. See RFA for more details.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. Applicants should be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) by 11:59 PM Eastern Time on the application due date. Late applications are generally not accepted for this funding opportunity announcement.

All applications must be submitted electronically through Grants.gov. Applicants should first review the Request for Application (RFA) that has been published in the Federal Register as well as the publication in the NIH Guide prior to getting started.

The proposed clinical protocol should be submitted to the applicable FDA IND or IDE Review Division a minimum of 30 days before the grant application deadline.

Pre-Application Registrations:

OPD Hint: *Applicants are encouraged to begin the pre-application/registration process* ***at least 4-6 weeks*** *prior to the grant submission date.*

Prior to electronically submitting a grant application, the following steps are required:

Step 1: Obtain a Data Universal Number System (DUNS) number

Step 2: Register with the System for Award Management (SAM) - A valid Taxpayer Identification Number (TIN) or Employer Identification Number (EIN) is necessary for SAM registration.

Step 3: Register with and obtain Username & Password on Grants.gov

Step 4: E-Business Point of Contact (EBiz POC) authorizes roles, which includes the Authorized Organization Representative (AOR) role on Grants.gov

Step 5: Track Role Request Status

Steps 1 through 5 above, in detail, can be found at:
http://www.grants.gov/web/grants/applicants/organization-registration.html

Step 6: Register with eRA Commons

General Application Instructions:

Application materials will open via Grants.gov approximately 60 days prior to the application receipt date. At that time (and after the pre-application process has been completed), applicants can download a copy of the application package on Grants.gov, complete it offline, and then upload and submit their application by following the instructions in the Apply for Grants link on the website.

Note: Not all the information in the Application Guide will apply to the Orphan Products Clinical Trials Grant application. Applicants are strongly encouraged to use the ''Tips'' posted on Grants.gov under the announcement number when preparing their submission.

Tips for Completing Form SF424 (R&R)

This is **not** a full instruction guide and does not cover all sections of the SF424 (R&R) forms. Please refer to the applicable SF424 (R&R) Application Guide posted by NIH for detailed instructions on completing the SF424 (R&R) forms.

The following are FDA/OPD specific items that you may need to complete the application.

Please note that the page limitations for the application are the same as the page limits on the Application Guide. Specifically, the Research Strategy section page limit is 12 pages.

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

- The applicant organization is ineligible.
- The application is received after the specified receipt date.
- The application is incomplete.
- The application is not responsive to the Request for Applications (RFA).
- The material presented in the application is insufficient to permit an adequate review.

A. SF424 (R&R) "APPLICATION FOR FEDERAL ASSISTANCE" (Page 1):

Type of Submission:
"Pre-application" is not used by this Agency.

Date Received by State/State Application Identifier:
Leave these fields blank.

Federal Identifier/Agency Routing Identifier:
If the "Type of Application" is "New" leave the Federal Identifier field blank, unless you are submitting a "Changed/Corrected" application in which case you need to enter the grants.gov tracking number (########) previously assigned.

Agency Routing Identifier:
Leave this section blank as it is not used by this Agency.

Type of Application:
For this RFA, the only application type allowed is "New."

Name of Federal Agency:
Enter "Food and Drug Administration" in this block.

Descriptive Title of Applicant's Project:
In the title block, be sure to include **ALL** of the following information in the order provided: (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.

OPD Hint: *Please note that the title field is limited to 200 characters, including the spaces between words and punctuation to avoid errors. An appropriate descriptive title example is "Ph **2a** Study of **Drug** for **Disease** IND **123,456** (**mm/dd/yyyy**)."*

OPD Hint: *The current version of the proposed clinical protocol that is included in the grant application should be submitted to the applicable FDA IND or IDE Review Division a minimum of 30 days before the grant application deadline. The **number of the assigned IND/IDE** and the **date of submission/amendment** of the proposed clinical protocol to the IND/IDE should be included on the SF424 Form (R&R) of the grant application along with the title of the grant in the "Descriptive Title of Applicant's Project" field.*

OPD Hint: *Use abbreviations as needed to ensure the descriptive title information is not truncated.*

Proposed Project (Start and Ending Date):
Start Date: This should be the date that the clinical trial is proposed to begin, not necessarily the date funding is expected.

Ending Date: This should be the date that the clinical trial is proposed to end.

B. SF424 (R&R) "APPLICATION FOR FEDERAL ASSISTANCE" (Page 2):

Estimated Project Funding:

Total Federal Funds Requested:
Enter total (direct and indirect) Federal funds requested from OPD for the entire project period for a maximum of 4 years of support.

Total Non-Federal Funds Requested:
Enter total amounts that will be used for this study that are not from federal sources. Please include sources and more detailed information on allocations in the budget justification sections.

C. SF424 "RESEARCH & RELATED Other Project Information":

Human Subjects:
All OPD grants involve human subject participation in a clinical trial, and are thus not exempt from Federal regulations regarding human subject protection. Always check "no" to the question "is the project exempt from Federal regulations?"

Vertebrate Animals:
"No" should be checked to "are vertebrate animals used."

Project Summary/Abstract (Project Description):
The Project Summary must contain a concise, self-contained summary of the proposed clinical study suitable for dissemination to the public. It should be informative to other persons working in the same or related fields and, insofar as possible, understandable to a scientifically or technically literate lay reader. The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the Orphan Products Clinical Trials Grants). The objectives of the project should be clearly stated by including such items as a brief background and rationale, hypotheses and expected results, specific aims, unique features, and study design and methods for achieving the stated goals. Make reference to the relevance of the project to the mission of the OPD grants program. Avoid describing past accomplishments and use of first person. Do not include proprietary or confidential information or trade secrets, as this description may be used for purposes other than review.

OPD Hint: *Be concise and succinct, but complete as* ***there is a one page limit for this section*** *(no longer than 30 lines of text). This page limit is based on a single-spaced page with 0.5 inch margins in 11 point font or larger. An abstract which exceeds this allowable length may be flagged as an error by the Agency upon submission. This would require a corrective action before the application can be accepted.*

Project Narrative (Public Health Relevance Statement):
This section represents a second component of the Project Summary, which is Relevance. In two or three sentences, describe the relevance of the project to public health using succinct, plain language that can be understood by a general, lay audience. There is a one page limit for this section.

Facilities and Other Resources:
Describe the resources available at each performance site. Describe how the scientific environment and existing resources in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, intellectual rapport, and database platforms). Describe any special facilities used for working with biohazards or other potentially dangerous substances. Information about select agents must be described in the Research Plan (Select Agent Research).

Note: Clinical Resources associated with the study performance site(s) need to be described in detail. A discussion of the resources available to the applicant to show that adequate enrollment can be achieved within the proposed timeframe of the study should be included, such as the number of patients presenting to the clinic yearly with the disease or condition that meet the proposed entry criteria of the study along with a discussion of any competing clinical trials or other potential barriers that may limit enrollment.

OPD Hint: *Failure to provide justification that adequate enrollment can be attained within the proposed study timeframe is a frequent weakness of OPD grant applications.*

Other Attachments: Foreign component:
Please provide justification if the proposed study requires the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States (US), or if the study requires the use of these to augment existing US resources. Indicate how the proposed project has specific relevance to the mission and objectives of FDA and has the potential for significantly advancing sciences in the United States.

"Senior/Key Person Profile (Expanded) Form":
Provide a Biographical Sketch (biosketch) for each senior/key person involved with the study. Key personnel include all principal investigators, co-investigators, and performance site investigators responsible for the design and conduct of the study.

OPD Hint: *Failure to include a detailed biosketch that supports the role of each senior/key person in the proposed study is a frequent weakness of OPD grant applications. A sample format of a biosketch can be found at* https://grants.nih.gov/node/826.

Budget:
The FDA OPD Grant Programs uses the Research & Related (R&R) Budget Component. Application budgets are not limited, but need to reflect the actual needs of the proposed project.

An applicant planning to submit a grant application with $500,000 or more in direct costs for any year is required to provide this notification in writing to the FDA OOPD Orphan Products Clinical Trials Grants Director a minimum of 4 weeks prior to the grant application submission deadline. Please see the following for more information: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental -instructions-forms-d.pdf

Applicants must provide a detailed budget for each requested year and attach a budget justification. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

The budget justification should:

- Clearly explain the rationale for all costs requested in the proposed project.
- Include a rationale if the budget has more than a standard escalation from the initial to the future year(s) of support.
- Explain any exclusions applied to the Facilities and Administrative (F&A) base calculation.
- Provide a rationale if any of the requested costs are higher than usual and customary.
- Be appropriate for the length of the study and not be padded to meet the maximal limitations of the RFA.
- Correlate with all costs specified in the detailed budget.
- State if the overall costs for the proposed study exceeds the limitations of this funding mechanism, and if so, explain how the additional costs to complete the proposed study will be covered (i.e. other grants, corporate funding, etc).
- State if other grants have been or will be applied for, and describe contingency plans should those funds not be obtained.

Note: The PHS 398 Modular Budget program does not apply to the OPD Clinical Trials grants and should not be used.

OPD Hint: *Failure to include a well justified budget (R&R Budget Component item K) is a frequent weakness of OPD grant applications.*

Budgets for Multiple Institutions: "R&R Subaward Budget Attachment(s) Form":

When multiple institutions are involved, one institution must be designated as the primary institution and funding for the other institution(s) must be requested via a subcontract to be administered by the primary institution. Individual budgets for all institutions that will be subcontracts should be attached separately to the Research & Related Subaward Budget Attachment(s) Form. A separate budget justification should also be submitted for each subaward.

D. SF424 "PHS 398 Research Plan":

The goal of FDA's OPD Clinical Trials Grants is to support clinical studies of products that address unmet needs in rare diseases or conditions or provide highly significant improvements in treatment or diagnosis. Through the support of efficient and innovative clinical studies evaluating safety and/or effectiveness, FDA expects to increase the number of treatments for rare diseases with an unmet medical need and support studies that will either result in market approval of these products or substantially contribute to the essential data needed for medical product development that will ultimately meet the needs of rare disease patients.

Application Type:

For this RFA all applications will be "New."

Research Plan Attachments:

The Research Plan should include sufficient information for evaluation of the project independent of other documents such as previous applications. Be specific

and informative, and avoid redundancies.

Note: Each of the items below should be saved and attached as a single file. Begin each text section of the Research Plan with a section header: Introduction, Specific Aims, Research Strategy, etc.

OPD Hint: *Please follow the page limitations for each section. Agency validations will include checks for page limits, which may result in errors. However, while these computer validations help minimize incomplete and/or noncompliant applications, they do not replace the validations conducted by FDA staff. Failure to comply with the requirements at any point may delay the review process.*

Specific Aims:

This section is limited to 1 page. Generally, this section begins with a brief narrative describing the overall goals and objectives of the project and the hypothesis to be tested. The section should concisely state how that will solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field and how that will either result in, or substantially contribute to, market approval of the proposed product and be followed by a list of the Specific Aims.

Research Strategy:

The entirety of the Research Strategy Section is limited to **12 pages**. Please note, FDA does not follow the order/headings that are included in the NIH's 424 R&R Application Guide.

The following sections should be included under the Research Strategy section of the application:

1. Rationale:

The soundness of rationale in relation to the current understanding of the rare disease(s) and the likelihood the proposal will facilitate medical product development to address an unmet medical need in a rare disease(s) or provide highly significant improvements in treatment or diagnosis and assist or substantially contribute to market approval of the proposed product(s).

- Description of the state of existing knowledge, including literature citations and highlights of relevant preliminary studies and previous preclinical and/or clinical data.
- Explanation of the importance of knowledge gap(s) and critical barrier(s) to progress in the field such as lack of treatments that the proposed project will address.
- Explanation of how the proposed study will either help support product approval or provide essential data needed for product development.

2. Study Design and Inclusion of Patient Input:

The quality and appropriateness of the study design, research methodology, and data analyses to accomplish the specific aims of the proposed study. Patients and

caregivers are highly encouraged to be involved in the planning of the design and development of these clinical studies. Their perspectives contribute to improved protocol design and medical product development through understanding of disease and treatment burden, impact on daily living and quality of life issues which may be otherwise overlooked.

- Description of the study including a clear hypothesis, study aims, and experimental design including how data will be collected, analyzed, and interpreted.
- Explanation of the use of different types of trial designs to meet objectives faster and more efficiently (basket, umbrella, platform trials).
- Description of plans to include patient/stakeholder input in study design and data elements.
- Description of the statistical analysis plan in adequate detail to show that the power of the study is sufficient to detect a meaningful benefit.
- Description of plans for ensuring data quality including but not limited to standardized data entry, data access, data monitoring, and compliance to good clinical practice.
- Description of plans for complying with human subjects protection and study monitoring.
- Discussion of challenges, potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims within a stated timeframe.

3. Investigator(s):
The qualifications of the Principal Investigator(s) (PIs), collaborators, and other support staff.

- Description of the competence of the PI(s), collaborators, and other support staff in conducting the proposed research, including their academic qualifications, research experiences, productivity, and any special attributes.
- If applicable, description of the rationale, leadership approach, governance, and organizational structure for a multi-PD/PI project.

4. Infrastructure and Resources:
The probability of success of the proposed project given the environment in which the work will be done.

- Description of evidence of the ability of the applicant to recruit and complete the proposed study within its budget and within stated time limits with the infrastructure in place including a timeline to implementation of the project.
- Description of institutional support, equipment, and other resources, such as with existing research networks, industry, academia and/or patient organizations and resource sharing plans as appropriate.
- Evidence that the product(s) to be studied is available to the applicant in the form and quantity needed for the clinical trial.

5. Ability to Advance the Current Field:
The ability of the project to shift current research or clinical practice paradigms

towards future product development and to exert a significant influence on product development.

- Explanation of how the proposed study will exert a sustained, powerful influence on the research field.
- Explanation of novel or improved concepts, approaches or methodologies, instrumentation or interventions to be developed or used, such as with pharmacokinetic, pharmacodynamic or clinical study designs (e.g. adaptive design trials, modeling, or simulations), and/or outcome measures, and their advantages over existing approaches.
- Description of plans for sharing/dissemination of data following completion of study.
- Explanation of sustainability plans beyond the proposed funding period and for acquiring alternative/additional funding if needed.

Rare Disease Prevalence:
The **Rationale Section of the Research Strategy** should also include a further subsection with the heading "Rare Disease Prevalence." This subsection should include **documentation to support that the estimated prevalence of the orphan disease or condition in the United States is less than 200,000 (or in the case of a vaccine or diagnostic, information to support that the product will be administered to fewer than 200,000 people in the United States per year).** For studies proposing assessing multiple rare diseases, supportive prevalence data for each rare disease is required.

Additional information may be required upon request, for example, regarding population estimate and rationale. This additional information may be required, in part, to assure that human clinical trials of drugs are eligible to receive funding under the OPD Grants Program.

OPD Hint: *Orphan drug designation is encouraged (although not required), especially if it is questionable whether the population served by the proposed use would qualify for orphan drug status.*

Support of Product Development:
The **Rationale Section of the Research Strategy** should also include a further subsection with the heading "Support of Product Development." This subsection should include an explanation of how the proposed study will either help support product approval or provide essential data needed for product development. If the proposal is for multiple products or multiple rare diseases, a plan as to how they intend to proceed with product development in collaboration with multiple sponsors is needed in the grant application.

Study Monitoring Plan:
The **Study Design and Inclusion of Patient Input Section of the Research Strategy** should include a further subsection with the heading "Study Monitoring Plan." This subsection should include a proposed plan for interim data monitoring. This section will detail who is to be responsible for interim monitoring (i.e., a DSMB, an SMC, or

the study investigator), what data will be monitored (i.e., performance and safety data only vs. efficacy data as well), the timing of the first data review (e.g., "the first interim look will occur when the initial 20 participants have completed the 6 month follow-up visit"), and the frequency of interim reviews (which will depend on such factors as the study design, interventions and anticipated recruitment rate). The plan will specify "stopping guidelines" and other criteria for the monitors to follow in their review of the interim data. Guidance on these topics is available at: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127073.pdf

Note: A preliminary monitoring plan must be submitted as part of the Research Plan portion of the grant application for a clinical trial. The plan will be examined as part of the peer review process, including evaluating the informed consent documents as well as the plan to monitor the integrity of the data collected and protocol compliance. Any comments and concerns will be included in an administrative note in the summary statement. OPD staff will ensure that all concerns are resolved before a grant award is made.

Letters of support:
Letters of support from the leader(s) of the existing clinical research institutions that will conduct the study indicating the sites that will be involved in the study, relevant resources and study infrastructure, and an estimate of the number of available eligible, relevant rare disease patients should also be provided.

Resource Sharing Plan:
Individuals are required to comply with the instructions for the Resource Sharing Plans as provided inthe SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

OPD Hint: *An inadequately justified or not well detailed statistical analysis is a frequent weakness noted by panel reviewers of OPD grant applications.*

Protection of Human Subjects:
The purpose of this section is to describe the involvement of human subjects to ensure the protection of the rights and welfare of the participants in a research project.

All institutions engaged in human subject research financially supported by HHS must file an assurance of protection for human subjects with the Office of Human Research Protections (OHRP) (45 CFR part 46). Applicants are advised to visit the OHRP Web site at http://www.hhs.gov/ohrp for guidance on human subject protection issues. Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).

The requirement to file an assurance applies to both awardee and collaborating performance site institutions. Awardee institutions are automatically considered to be engaged in human subject research whenever they receive a direct HHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. In such cases, the awardee institution bears the responsibility for protecting human subjects under the award.

The awardee institution is also responsible for, among other things, ensuring that all collaborating performance site institutions engaged in the research hold an approved assurance prior to their initiation of the research. 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. An awardee institution must, therefore, have an IRB of record and assurance. 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 OHRP.

OPD Hint: *Failure to submit at least a draft consent/assent form is a frequent weakness noted by panel reviewers of OPD grant applications.*

Note: While IRB approval is not needed at time of submission of a grant application, IRB approval from the IRB of record must be on file with the FDA grants management office before an award to fund the study will be made. If IRB approval has been attained, please specify such in this section and include a copy of the approval letter.

Inclusion of Women and Minorities:

This section is required for applicants answering "yes" to the question "Are human subjects involved?" on the R&R Other Project Information Cover Page and the research does not fall under Exemption 4.

When the proposed project involves human subjects and/or FDA-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals:

Not applicable for OPD grants.

Select Agent Research:

Typically not applicable for OPD grants.

Multiple PD/PI Leadership Plan:

For applications designating multiple PDs/PIs, a new section of the research plan, entitled Multiple PD/PI Leadership Plan [Section 10 of the Research Plan Component in the SF424 (R&R)], must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the

leadership team and the research project should be described, and should include communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award (NoA).

Appendix:

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide with the following additional instructions:

The Appendices should include the following, as appropriate for the proposed study:

- Protocol: The full final protocol must be provided in an appendix section.
- Informed Consent: Consent forms, assent forms, and any other information given to a subject are part of the grant application and must be provided, even if in a draft form. The consent forms should be attached in an appendix section. The applicant is referred to HHS and FDA regulations at 45 CFR 46.116 and 21 CFR 50.25 for details regarding the required elements of informed consent.
- Product Availability: There must be evidence that the product(s) to be studied is available to the applicant in the form and quantity needed for the clinical trial proposed. A current letter from the supplier as an appendix will be acceptable. If negotiations regarding the supply of the study product(s) are underway but have not been finalized at the time of application, please provide a letter indicating such in the application. Verification of adequate supply of study product(s) will be necessary before an award is made.
- Letters of collaboration/support for conduct of the study.
- If an applicant is submitting a grant application with $500,000 or more in direct costs for any year, the applicant is required to include the letter of approval for submission of that budget from the FDA Orphan Products Grants Program Director as an appendix to the application.

An application that does not observe the required page limitations may be delayed or rejected in the review process. Applicants **must** follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (See http://grants.nih.gov/grants/funding/424/index.htm)

OPD Hint: *Missing study protocols and informed consent/assent documents are a frequent weakness noted by panel reviewers of OPD grant applications. A draft form of these documents should be submitted if a final form is not yet available.*

Items that should **not** be included in the appendix:

- Photographs or color images of gels, micrographs, etc., **are no longer accepted as Appendix material**. These images must be included in the Research Strategy PDF. However, images embedded in publications are allowed.
- Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.

Note: All attachments must in PDF format only and not be password protected. **There is a limit of 10 appendices total.** If the pages in any attachment are greater than 11 x 11 inches or less than 8.5 x 8.5 inches, please adjust with software that can change the page size from actual to an 8.5 x 11 inch size. See the applicable SF424 (R&R) Application Guide at http://grants.nih.gov/grants/how-to-apply-application-guide.htm for page limitations and appendix guidance in detail.

Applicants are encouraged to be as concise as possible while including the information needed for expert scientific review of their proposal; however, the appendices should not be used to circumvent page limitations, such as the specified page limit for the Research Strategy.

OPD Hint: *It is recommended that all appendices be given a name that is meaningful to reviewers rather than relying on sequential order. Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all the items included as appendices is also encouraged, but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the appendix requirements may be delayed in the review process. Extensive appendices are noted by panel reviewers of OPD grant applications as being extremely difficult to review in their entirety.*

E. Other Information:

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

- **Federal Wide Assurance**
  Federal Wide Assurance (FWA or assurance) obtained from Office for Human Research Protections (OHRP) 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.
- **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.

- **IND/IDE**
  All new and continuing grants must comply with all regulatory requirements necessary to keep the status of their IND/IDE active and in effect, that is, not on clinical hold. Only medical foods that do not need pre-market approval and devices that are classified as non-significant risk (NSR) are free from these IND/IDE requirements.

Useful links:
OOPD Web Page:
(http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm2005525.htm)

RFA Link:
http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-15-001.html

Grants 101:
http://www.grants.gov/web/grants/learn-grants/grants-101.html

eRA:
Creating User Accounts
(http://grants.nih.gov/grants/ElectronicReceipt/files/Grantee_Registration_Process_for_Commons.pdf)
(https://commons.era.nih.gov/commons-help/174.htm)

Federal Wide Assurance:
Office for Human Resource Protections
(http://www.hhs.gov/ohrp/)
(http://ori.hhs.gov/reg-sub-part-a)
(http://ori.hhs.gov/phs-admin-action-bulletin-board)

Data Universal Number System (DUNS) number:
(http://fedgov.dnb.com/webform)

System for Award Management (SAM):
(https://governmentcontractregistration.com/default.asp?key=sam&source=bing)

Credential Provider registration:
(https://apply07.grants.gov/apply/OrcRegister)

HHS/Financial Management:
(https://rates.psc.gov/)

Orphan Research Grants Program Resource List:
Grants.Gov Submitting your Application
(http://grants.nih.gov/grants/submitapplication.htm)
NIH Forms and Applications (http://grants.nih.gov/grants/forms.htm)

Salary Cap Summary (FY 1990 to Present)

(http://grants.nih.gov/grants/policy/salcap_summary.htm)

Grants.gov Registration Instructions for Domestic and Foreign Organizations:
Grantee Registration Process in NIH eRA Commons: Detailed Steps
(http://grants.nih.gov/grants/ElectronicReceipt/files/grantee_registration_process_for_commons.pdf)

Additional Grants.gov Electronic Submission Process Resources: Grants.gov Applicant FAQs:
(http://www.grants.gov/web/grants/applicants/applicant-faqs.html)
How to Apply – Application Guide:
(http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm)