Obstetric-Fetal Pharmacology Research Center (OPRC): Pre-Application Webinar

Preparing to submit a U54 Application for OPRC (RFA-HD-14-013)

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Zhaoxia Ren, MD, PhD

Obstetric and Pediatric Pharmacology and Therapeutics Branch, NICHD

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Outline

- Request for Applications (RFA) Overview (Dr. Zhaoxia Ren)
  - Background
  - Timelines
  - RFA Purpose
  - Requirements RFA Overview
- Review of Applications (Dr. Sherry Dupere)
- Q & A Session (Dr. Zhaoxia Ren)

Background

- Reissue of RFA for Obstetric-Fetal Pharmacology Unit (OPRU) Network
- New grant mechanism (U54) with specialized Centers (OPRCs)
- Emphasis on translational/basic mechanistic studies

Timeline for the RFA-HD-14-013

- Letter of Intent: November 9, 2014
- Receipt Date: December 9, 2014
- Peer Review: March 2015
- Council Review: May 2015
- Earliest Start Date: July 2015

Letter of Intent

- Draft OPRC Title
- RFA ID
- Principal Investigator with contact information
- Other Key Personnel
- Participating Institutions
- (Optional: Brief description of projects)

Eligibility

- Principal Investigator (PI)
  - Serves as the Center Director of the OPRC
  - Should be an established investigator with MD or PhD degree and record of external funding
  - PharmD or other doctoral degrees with expertise in clinical research and capability of enrolling patients or strong basic science research background and experience in the field

Purpose of the RFA

- Support specialized centers (OPRCs) for:
  - Multidisciplinary basic and translational research in obstetric-fetal pharmacology and therapeutics
  - Collaborative clinical pharmacological research in pregnant women
  - Training of investigators in basic/translational and/or clinical research of obstetric pharmacology

Goal of the OPRCs

- Advance knowledge in obstetric pharmacology to improve the safety and effectiveness of drug treatment of diseases/conditions in women during pregnancy

Requirements of a U54 Application

- Components of the OPRC
  - Administrative Core
    - Training Program
  - Research Projects
    - Basic/Translational Research
    - Clinical Research
    - Pilot Project (optional)
  - Logistic Coordinating Core (Optional)

See RFA for detailed description of each component

Page Limitations

- Overall: 12 pages
- Administrative Core: 12 pages
- Research Projects:
  - Clinical Concept Proposal: 6 pages
  - Basic/Translational Research: 6 pages
  - Pilot Project: 6 pages
- Logistic Coordinating Core (LCC): 6 pages

Award Budget

- Total direct costs no more than $530,000 per year
  - Administrative Core
    - Must include $30,000 per year for training
    - Up to $50,000 per year for one or more pilot projects in year 01 and 02
- Logistic Coordinating Core
  - Total budget no more than $150,000 per year
  - One Center will be awarded for the OPRCs

Review of Applications

- Peer review by an ad hoc review committee
- Organized by NICHD Scientific Review Branch
- Special instructions given to reviewers
- Review criteria for each component of the OPRC
- See RFA for all review criteria

Question & Answer Session

1. Will there be an open competition for a centralized DCC?

No. There will be no centralized DCC for the OPRCs.

2. We are interested in including a LCC component but have concerns about the review of LCC. If the LCC component scores poorly, would that affect an overall OPRC application score?

The LCC component will receive separate review and score that will count for overall impact score for the application. (Dr. Sherry Dupere will cover details in her presentation)

3. Will multiple PIs be considered a strength or limitation given the complexity of the different core components of the grant?

Multiple PIs are allowed in this RFA. Applicants should management and coordination plan as well as PIs' commitment to the centers/project.

Question & Answer Session

4. For clinical research project, will the proposal include clinical pharmacology studies to collect outcomes on efficacy and safety (Phase I or II) or large studies to evaluate efficacy and safety (Phase III)?

The OPRC clinical research only include phase I and/or II studies, not phase III studies.

5. What is role of the LCC PI in the OPRC? Can the LCC PI be involved in OPRC studies?

The LCC is not a DCC and only provides coordination and logistic services and will not provide statistical services. The PI of the LCC will not participate in any of the OPRC studies.

Question & Answer Session

6. Does the write up of a pilot research project go in the admin core or in the research project?

The write up of a pilot project should be an independent research project and separated from the admin core. However, budget of the pilot project is under the admin core budget.

7. Whether a psychiatrist as Director would be seen as competitive with a strong Ob and Pharm team?

A psychiatrist would be eligible, but the reviewers might indeed consider someone with ObGyn or PharmD credentials to be better qualified. So, it might be a good idea to have that expertise on the team – either as Multiple PI(s) or co-investigator(s).

Question & Answer Session

8. Page limits for the Admin Core, which documents are included in the 12 page limits?

The 12 page limit only includes research plan and does not count for other information such as the cover page, budget, biosketches, etc.

9. Will there be capitation funds offered for patient costs that are outside the annual direct costs or not part of the Center's annual direct cost cap?

With an U54 mechanism, there will not be capitation funds usually managed by DCC. The costs for proposed clinical studies/trials should be included in the budget of clinical component of the Center.

Question & Answer Session

10. Is there another DCC identified for the next cycle?

No, there will be no DCC for the next cycle under this RFA (U54)

11. For each application, the total direct cost budget cannot exceed $530,000 per year. If we choose to apply for the LCC, is the budget allowance for the LCC ($150,000) above the $530,000 or would $530,000 still be the budgetary cap?

The budget for LCC ($150K) is a separate budget and does not count for the ($530K) total DC for the OPRC.

Question & Answer Session

12. Should our budget include the estimated costs of conducting the proposed research projects?

Yes.

13. If yes, should this include the cost to conduct the project at our site or for all sites within the ORPCs?

The estimated costs are for your proposed research projects and should not include the costs for other sites.

14. Is there an expectation for a project focused on fetal /newborn pharmacology in the OPRCs?

The proposal could study the fetal/newborn but should focus on pregnant women.

Question & Answer Session

15. What can the required 30K for training support ?

The required 30K allotted for training support will cover expenses related to training (similar to budget for a training grant).

16. If someone is 20% on Admin Core, can that persone have additional percent effort on the scientific projects or other cores? Is there a max per person?

There is no max per person in efforts for the Center Director as long as his/her total efforts not exceed 100%. A Center Director can also serve as a PI or co-PI on other projects of the OPRC.

Question & Answer Session

17. How will the data management/statistical support be accommodated, by site by project proposed or centrally at NICHD?

Each site will provide its own data management and statistical analysis service to the studies proposed by the site.

18. The direct cost cap is $530,000. When developing a budget for this proposal, are costs of a proposed logistics core excluded in the total direct cost calculation to determine whether the budget is over or under the cap?

Similar to #11

19. If a pilot project is proposed, are the costs exclusive of the direct cost cap calculation?

The budget for pilot project ($50K) is included in the Admin Core budget

Question & Answer Session

20. What are the page limitations of the pilot project research plan?

6 pages

21. Must the clinical project and the translational project run concurrently for the entire 5 year project period?

The clinical and translational projects can run concurrently but should not run more than 5 years.

22. Does the translational project has to be approved by the steering committee prior to implementation or do we assume that if our center wins a spot in the OPRC that the translational project will be funded?

The translational project does not need the steering committee's approval for implementation.

Questions

- Scientific and Research Program
  - Zhaoxia Ren, MD, PhD
  - 301-402-9340
  - zren@mail.nih.gov
- Review
  - Sherry Dupere, PhD
  - 301-451-3415
  - duperes@mail.nih.gov
- Grants Management
  - Bryan S. Clark, MBA
  - 301-435-6975
  - clarkb1@mail.nih.gov

All slides will be posted at NICHD website:

https://www.nichd.nih.gov/about/org/der/branches/opptb/Pages/overview.aspx

Eunice Kennedy Shriver National Institute of Child Health and Human Development