NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support **16 Feb 2015**

[Click on blue hyperlink for further information]

*The NIH funding opportunities listed below are only a **selection** of pre-screened, currently open health funding opportunities for which **South African institutions are eligible to apply**. For a comprehensive selection of NIH funding opportunities, please visit www.grants.nih.gov.*

*Please be advised that you **must contact the Research Grants Management Office (RGMO) at least 60 days before the submission date**, Mr Eugene Baugaard (eugeneb@sun.ac.za), or as soon as you commit to apply for an NIH grant and that the grant is submitted institutionally.*

Important notices

- **Delays in Grant Application Submission due to Severe Winter Storms (NOT-OD-15-066)**
- **Request for Proposals (RFP) Notice: Preclinical Prevent Cancer Program: Preclinical Efficacy and Intermediate Endpoint Biomarkers (NOT-CA-15-013)**
- **Request for Proposals (RFP) Notice: Preclinical Prevent Cancer Program: Toxicology and Pharmacology Testing (NOT-CA-15-014)**
- **Request for Information: NHLBI Whole Genome Sequencing Project (NHLBI-WGS) (NOT-HL-15-253)**
- **Request for Information (RFI) on the Draft 2015 Action Plan for the Muscular Dystrophies (NOT-NS-15-014)**
- **Request for Information (RFI): The Impact of Environmental Lead Exposure on Cognition and Bone Function (NOT-TW-15-002)**

1. Title: Molecular Mechanisms of Combination Adjuvants (MMCA)

Letter of Intent due date: at least 30 days prior to the application due date **Hyperlink:** (RFA-AI-15-005) **Type:** UO1
Application Due Date: July 9, 2015 by 5:00 PM local time of applicant organization.
Purpose: This FOA solicits applications that propose studies of the mechanism of action of a combination of two or more vaccine adjuvants (combination adjuvant). Adjuvants that are used in these studies must already have shown immune boosting activity when used individually in licensed or unlicensed vaccines (e.g. experimental or candidate vaccines). The purpose of this FOA is to build upon the investment the NIAID has already made into adjuvant research, by combining previously identified and characterized adjuvants and characterizing their immune stimulating activity. The Cooperative Agreement grant mechanism allows for coordination of these research efforts with NIAID's overall adjuvant research objectives. The long-term goal is to promote the development of novel adjuvant combinations which will improve the immunogenicity of vaccines while addressing concerns related to reactogenicity.
Budget: The application budget is limited to $350,000 in direct costs per year, and should reflect the actual needs of the project. The scope of the proposed project should determine the project period. The maximum project period is five years.

2. Title: Advancing Exceptional Research on HIV/AIDS and Substance Abuse

Letter of Intent due date: at least 30 days prior to the application due date **Hyperlink:** (RFA-DA-16-001) **Type:** R01
Application Due Date: July 31, 2015, by 5:00 PM local time of applicant organization.
Purpose: This FOA will support highly innovative R01 applications on HIV/AIDS and drug abuse and will complement the Avant-Garde Award Program for HIV/AIDS research. The Avant-Garde award supports individuals who conduct high-risk, high-reward research and does not require a detailed research plan. Applications submitted under this FOA are required to have a detailed research plan and preliminary data. This FOA focuses on innovative research projects that have the potential to open new areas of HIV/AIDS research and/or lead to new avenues for prevention and treatment of HIV/AIDS among substance abusers. The nexus with substance abuse should be clearly described. This FOA is open to both individual researchers and research teams and is not limited to any one area of research on HIV and substance use.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

3. Title: Dissolution Methods for Long-acting Levonorgestrel Intrauterine System

Letter of Intent due date: March 6, 2015, by 11:59 PM Eastern Time **Hyperlink:** (RFA-FD-15-006) **Type:** UO1
Application Due Date: April 27, 2015, by 11:59 PM Eastern Time.
Purpose: There is a lack of compendial or biorelevant in vitro drug release assays for long-acting contraceptive intrauterine systems. The objective of this study is to investigate dissolution methods, both real time and accelerated conditions, for levonorgestrel intrauterine system (5-year application) and to analyze their capability of detecting manufacturing differences, predicting in vivo performance, and to evaluate method robustness. The results from this study will help the FDA in developing recommendations to determine bioequivalence of generic ***intrauterine*** systems.
Budget: Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect): YR 01: $125,000 YR 02: $125,000 YR 03: $ 50,000 YR 04: $ 25,000 YR 05: $ 25,000. The scope of the proposed project should determine the project period. The maximum project period is five (5) years.

4. Title: Dissolution Methods for Long-acting Periodontal Drug Products

Letter of Intent due date: March 6, 2015 by 11:59 PM Eastern Time. **Hyperlink:** (RFA-FD-15-007) **Type:** UO1

Application Due Date: April 27, 2015 by 11:59 PM Eastern Time.

Purpose: There is a lack of compendial or biorelevant in vitro drug release assays for long-acting periodontal dosage forms. These products include biodegradable microspheres, in situ forming implants and matrix tablets. The purpose of this study is to develop a bio-relevant dissolution method for a long-acting periodontal dosage form and to identify the drug product's key physicochemical attributes that affect the drug dissolution behavior and bioavailability. The results from this study will help the FDA in developing recommendations to determine bioequivalence of generic long-acting ***periodontal*** drug products.

Budget: Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect): YR 01: $125,000 YR 02: $125,000. The scope of the proposed project should determine the project period. The maximum project period is two (2) years.

5. Title: Pharmacometric Modeling and Simulation for Long Acting Injectable (LAI) Products

Letter of Intent due date: March 6, 2015 by 11:59 PM Eastern Time. **Hyperlink:** (RFA-FD-15-008) **Type:** UO1

Application Due Date: April 27, 2015 by 11:59 PM Eastern Time.

Purpose: Subtopic 1: conduct physiologically-based pharmacokinetic modeling (PBPK) to relate critical quality attributes to in vivo performance for bioequivalence (BE) evaluation; **Subtopic 2:** perform population pharmacokinetic-pharmacodynamic (PK-PD) modeling and statistical analysis to identify ways to reduce residual variability and identify appropriate PK metrics, enabling BE assessment in parallel BE studies with acceptable sample size. The findings from these studies will help establish scientific and regulatory standards for ensuring therapeutic equivalence of generic LAI products.

Budget: Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect): Subtopic 1: YR 01: $200,000 YR 02: $200,000 YR 03: $200,000 Subtopic 2: YR 01: $200,000 YR 02: $200,000 YR 03: $200,000 Applicants may apply for and receive funding for more than one subtopic; however a separate application must be submitted for each subtopic. The scope of the proposed project should determine the project period. The maximum project period is three (3) years.

6. Title: NIDCD Phase I/II/III Clinical Trials in Communication Disorders

Letter of Intent due date: at least 30 days before the application due date **Hyperlink:** (PAR-15-116) **Type:** UO1

Application Due Date: June 9, 2015; October 9, 2015; February 9, 2016; June 9, 2016; October 11, 2016; February 9, 2017; June 9, 2017; October 10, 2017, by 5:00 PM local time of applicant organization

Purpose: The NIDCD is committed to identifying effective interventions for the treatment or prevention of communication disorders by supporting robust, well-designed, and well-executed clinical trials. This funding opportunity announcement (FOA) supports a cooperative agreement between NIDCD Project Scientist and investigator to support phase I and II clinical trials of preliminary efficacy and phase III clinical trials of definitive efficacy. Phase III clinical trial applications must include a complete detailed Manual of Procedures (MOP) in the appendix (see http://www.nidcd.nih.gov/research/clinicaltrials for an example of a complete, detailed MOP). The NIDCD Planning Grant for Phase III Clinical Trials in Communication Disorders (U34) (PAR-15-117) may be used to gather information and prepare the MOP.

Budget: Application budgets are not limited, but must reflect actual needs of the proposed project. The maximum project period is five years.

7. Title: NIDCD Planning Grant for Phase III Clinical Trials in Communication Disorders

Letter of Intent due date: 30 days before the application due date **Hyperlink:** (PAR-15-117) **Type:** U34

Application Due Date: June 9, 2015; October 9, 2015; February 9, 2016; June 9, 2016; October 11, 2016; February 9, 2017; June 9, 2017; October 10, 2017, by 5:00 PM local time of applicant organization.

Purpose: The NIDCD is committed to identifying effective interventions for the treatment or prevention of communication disorders by supporting robust, well-designed, and well-executed clinical trials. This funding opportunity announcement (FOA) supports a cooperative agreement between NIDCD Project Scientist and investigator for a planning grant for phase III clinical trials of definitive efficacy. The NIDCD Planning Grant for Phase III Clinical Trials in Communication Disorders (U34) is used to support the refinement of the multicenter randomized phase III clinical trial protocol and procedures and the development of a detailed Manual of Procedures (MOP) (see http://www.nidcd.nih.gov/research/clinicaltrials for an example of a complete, detailed MOP). Consultation with NIDCD Scientific/Research staff is strongly encouraged prior to the submission of the U34 application.

Budget: Total direct costs are limited to $275,000 over a two-year period, with no more than $200,000 in direct costs allowed in any single year.

8. Title: Identification of Genetic and Genomic Variants by Next-Gen in Sequencing Non-human Animal Models

Letter of Intent due date: N/A **Hyperlink:** (PAR-15-120) **Type:** UO1

Application Due Date: June 30, 2015; October 20, 2015; March 1, 2016; June 30, 2016; October 20, 2016; March 1, 2017; June 30, 2017; October 20, 2017; March 1, 2018, by 5:00 PM local time of applicant organization

Purpose: The goals of this initiative are to identify gene variants of traits associated with addiction and substance abuse in selectively bred, and outbred non-human animal models using methodologies of Next Gen-Sequencing, mapping, and genotyping. This FOA will replace PAR-14-010 "Identification of Gene Variants for Addiction Related Traits by Next-Gen Sequencing in Model Organisms Selectively Bred for Addiction Traits (UH2/UH3)".

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

Brief definitions of some NIH grant mechanisms: **comprehensive list of extramural grant and cooperative agreement activity codes**

U01 – NIH Research Project Cooperative Agreement: supports discrete, specified, circumscribed projects to be performed by investigator(s) in an area representing their specific interests and competencies; many types of cooperative agreements, e.g. Clinical Trials Centers; generally no budget upper limit but may be specified.

R01 – NIH Research Project Grant Program: most common NIH program; to support a discrete, specified, circumscribed research project; generally 3-5 years; budget may be specified, but generally <$500,000 p.a. (direct costs).

R03 – NIH Small Grant Program: limited funding for short period to support e.g. pilot / feasibility study, collection of preliminary data, secondary analysis of existing data, small-contained research projects, development of new research technology, etc.; normally for "new investigators"; not renewable; up to 2 years; budget generally <$50,000 (direct costs).

UH2/UH3 - Phase Innovation Awards Cooperative Agreement: Exploratory/Developmental Cooperative Agreement Phase I and II. To support the development of new research activities in categorical program areas (Support generally is restricted in level of support and in time.) The UH3 award is to provide a second phase for the support for innovative exploratory and development research activities initiated under the UH2 mechanism. Although only UH2 awardees are generally eligible to apply for UH3 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under UH2.

R21 – NIH Exploratory/Developmental Research Grant: encourages new, exploratory and developmental research projects (could be used for pilot or feasibility studies); up to 2 years; budget total generally <$275,000 (direct costs).

R21/R33 - Phased Innovation: The R33 award is to provide a second phase for the support for innovative exploratory and development research activities initiated under the R21 mechanism. Although only R21 awardees are generally eligible to apply for R33 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under R33.

Complete Glossary and acronym list of NIH Terms

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