NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 4 August 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. **All final application documents MUST reach the RGMO seven (7) workdays before NIH application due date**.*

Important notices

- **Applicants should be aware that on-time submission means that an application is submitted error free to of both Grants.gov and eRA Commons.**
- **All final application documents MUST reach the RGMO seven (7) workdays before NIH application due date. Internal Submission will be 2 days before the application due date.**
- **Late applications will not be accepted for any FOA.**
- **Findings of Research Misconduct (NOT-OD-15-131)**
- **Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice (NOT-OD-15-128)**
- **Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice (NOT-OD-15-129)**
- **Subscribe to Receive NIH eRA Service Information (NOT-OD-15-132)**
- **Request for Information (RFI): Development of Multivalent Vaccine Candidates For Filovirus and Lassa Fever (NOT-AI-15-049)**
- **AHRQ Announces Interest in Innovative Methods Research to Increase the Utility of Systematic Reviews (NOT-HS-15-011)**

1. Title: BRAIN: Theories, Models and Methods for Analysis of Complex Data from the Brain

Letter of Intent due date: September 21, 2015 **Hyperlink:** (RFA-EB-15-006) **Type:** RO1

Application Due Date: October 21, 2015, by 5:00 PM local time of applicant organization. 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 to of both Grants.gov and eRA Commons.*** Internal Submission will be 2 days before the application due date above.

Purpose: This FOA solicits new theories, computational models, and statistical methods to derive understanding of brain function from complex neuroscience data. Approaches could include the creation of new theories, ideas, and conceptual frameworks to organize/unify data and infer general principles of brain function; new computational models to develop testable hypotheses and design/drive experiments; and new mathematical and statistical methods to support or refute a stated hypothesis about brain function, and/or assist in detecting features in complex brain data. It is expected that the approaches developed under this FOA will be made widely available to the neuroscience research community for their use and modification.

Budget: Application budgets not limited, but are expected to range between $150,000 to $250,000 direct costs per year. Investigators are expected to request a budget that is required to accomplish the proposed work. Awards are for three years of support.

2. Title: Building towards Statistically-Based Pharmaceutical Quality Standards (FDA)

Letter of Intent due date: N/A **Hyperlink:** (RFA-FD-16-003) **Type:** UO1

Application Due Date: October 16, *2015, by 8:00 PM Eastern Time.* 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 8:00 PM Eastern Time on the application due date. Internal Submission will be 2 days before the application due date above.

Purpose: The goal of this project is to generate data and develop a statistical sampling and analysis strategy to aid FDA/CDER policy in drafting data-based guidance in support of the use of appropriate statistical tools and standards. Specifically, the development of standards for statistical methods suitable for lot release which could be used to drive industry towards increased product and process understanding throughout the lifecycle of a product. The project will provide data, sampling and data analysis approaches to inform for the agency and the human pharmaceutical industry to advance the development of risk- and science-based standards. These projects could be split into subsets by product type, process type, manufacturing complexity and/or therapeutic index to facilitate understanding

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: $1,000,000; YR 02: $500,000; YR 03: $500,000 The scope of the proposed project should determine the project period. The maximum project period is three (3) years

3. Title: Evaluating Quality Metrics for Risk-Based Surveillance of Drug Manufacturing Operations and Facilities (FDA)

Letter of Intent due date: N/A **Hyperlink:** (RFA-FD-16-004) **Type:** UO1

Application Due Date: October 16, *2015, by 8:00 PM Eastern Time.* 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 8:00 PM Eastern Time on the application due date. Internal Submission will be 2 days before the application due date above.
Purpose: The goal of this project is to evaluate a set of potential quality metrics for their utility in monitoring quality across the pharmaceutical manufacturing sector. This project aids to support FDA's efforts in transforming quality oversight from a qualitative to a quantitative and expertise-based assessment in order to assure that quality drugs are available to the American public. The outcomes of the project could also be used to assist in the development of a risk-based inspection approach for domestic and foreign drug establishments.
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: $500,000; YR 02: $500,000. The scope of the proposed project should determine the project period. The maximum project period is two (2) years.

4. Title: Research to Advance Vaccine Safety

Letter of Intent due date: N/A **Hyperlink:** (PA-15-312) **Type:** R01
(PA-15-313) R21

Application Due Date: Standard dates apply RO1: 5 Feb; 5 Jun; 5 Oct by 5:00 PM local time of applicant organization. Aids Dates 7 Jan; 7 May; 7 Sep by 5:00 PM local time of applicant organization. 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 the application due date. Internal Submission will be 2 days before the application due date above. **Expiry date:** September 8, 2018
Purpose: The purpose of this funding opportunity announcement (FOA) is to support research that will contribute to the overall understanding of vaccine safety. This research opportunity encourages studies that address scientific areas potentially relevant to vaccine safety such as 1) physiological and immunological responses to vaccines and vaccine components, 2) how genetic variations affect immune/physiological responses that may impact vaccine safety, 3) identification of risk factors and biological markers that may be used to assess whether there is a relationship between certain diseases or disorders and licensed vaccines, 4) creation/evaluation of statistical methodologies for analyzing data on vaccine safety, including data available from existing data sources such as passive reporting systems or healthcare databases, or 5) the application of genomic/molecular technologies and systems biology approaches to evaluate vaccine safety. This FOA aligns with the research goals and objectives outlined in the U.S. National Vaccine Plan.
Budget: **RO1:** Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum period is 5 years. **R21:** The combined budget for direct costs for the two year project period may not exceed $275,000. No more than $200,000 may be requested in any single year.

5. Title: Discovery of Genetic Basis of Monogenic Heart, Lung, Blood, and Sleep

Letter of Intent due date: 30 days prior to the application due date **Hyperlink:** (PAR-15-314) **Type:** X01
Application Due Date: October 20, 2015; June 15, 2016; June 15, 2017; June 15, 2018 by 5:00 PM local time of applicant organization. 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 the application due date. Internal Submission will be 2 days before the application due date above. **Expiry date:** July 12, 2018
Purpose: This Funding Opportunity Announcement (FOA) invites applications to use the genome-wide sequencing capacity of the Centers for Mendelian Genomics to carry out studies of the genetic basis of Mendelian or monogenic disorders that significantly affect heart, lung, blood, and sleep (HLBS) systems.
Budget: Not applicable. Funds are not awarded via this X01 resource access award. The maximum project period is 4 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).
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