# NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 13 May 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**

- **ASSIST Now an Option for R01 and Individual Career Development Award Applications (NOT-OD-15-098)**
- **ASSIST Now an Option for Research Project Cooperative Agreements (U01s) (NOT-OD-15-099)**
- **Notice of Intent to Publish a Funding Opportunity Announcement for NLM Administrative Supplements for Informationist Services in NIH-funded Research Projects (Admin Supp) (NOT-LM-15-006)**
- **Findings of Research Misconduct (NOT-OD-15-100)**
- **Notice of Applicant Information Webinar for the NIBIB Program on Pediatric Research using Integrated Sensor Monitoring Systems (PRISMS): U01, U54, U24 (NOT-EB-15-007)**
- **Notice of Intent to Publish a Funding Opportunity for a Clinical Trials Network for Emergency Care Research: Regional Clinical Centers (U24) (NOT-NS-15-021)**

**1. Title: Characterization of Pro- and Anti-Geronic Proteins and Peptides**

**Letter of Intent due date:** 30 days before the application due date **Hyperlink:** (RFA-AG-16-005) **Type:** RO1
**Application Due Date:** July 9, 2015, by 5:00 PM local time of applicant organization
**Purpose:** The goal of this FOA is to advance research on naturally occurring proteins (and/or peptides) known to impact one or more aging phenotypes, at physiological levels, based on whole-animal experimental evidence. These are "geronic proteins" isolated from circulation, which might reverse (rejuvenate) or potentially prevent development of aging phenotypes observable in an older laboratory animal, such as cardiac hypertrophy, diminished skeletal muscle repair-efficiency, reduced muscle strength, etc. (anti-geronic proteins), or which appear to promote an aging phenotype in a young adult laboratory animal, such as leading to decreased neurogenesis or cognitive function (pro-geronic proteins). (For brevity, this definition includes "geronic peptides.") The pro- or anti-geronic functions of these proteins have been demonstrated to have physiological consequences at least at the level of tissue or organ function, but often have additional support for their geronic functions at the cellular and molecular levels (but, importantly, in whole-animal experiments). These anti- and pro-geronic proteins are often known to function in other biological contexts, such as development. The primary goals of this FOA are to characterize the "geronic functions" of these proteins. The outcome of research supported by this FOA should be an improved understanding of the range of aging phenotypes affected by geronic proteins (individually or in concert), the cellular and molecular mechanisms by which these geronic functions are exerted, and will eventually promote studies supporting the translational potential of these proteins.
**Budget**: Application budgets need to reflect the actual needs of the proposed project but should not exceed $350,000 per year in direct costs. The maximum project period is 5 years.

**2. Title: Innovation for HIV Vaccine Discovery**

**Letter of Intent due date:** 30 days before the application due date **Hyperlink:** (RFA-AI-15-019) **Type:** RO1
**Application Due Date:** July 29, 2015, by 5:00 PM local time of applicant organization
**Purpose:** The purpose of this FOA is to encourage applications proposing innovative, high risk, high impact research to identify novel HIV vaccine concepts and targets. A further focus is to answer important scientific questions that will aid in the design and development of an effective immunogen that may provide long-term safe protection from either acquisition of or ongoing infection by HIV. Thus, this FOA aims to support early discovery research by supporting the testing of novel hypotheses and approaches, and to reward initial success with continued funding that is dependent upon achieving applicant-proposed and pre-award negotiated "Go/No-Go criteria" by the year-2 progress report.
**Budget**: Application budgets are limited to $350,000 per year in direct costs. Applicants may request up to an additional $150,000 in direct costs per year in any year when research in nonhuman primate or humanized mice models is proposed and justified. Applicants should submit a 4 year R01 application, and are required to identify Go/ No-Go decision criteria to be achieved as deliverables for the Year 2 progress report. Achievement of the stated goal(s) (Go) will enable continuation of the R01 for a total of 4 years, while failure to achieve the stated goal(s) (No-Go) will result in negotiation of a reduced budget for Year 3 and award close out.

**3. Title: NIH-PEPFAR Collaboration on Implementation Science for HIV: Towards an AIDS-free Generation**

**Letter of Intent due date:** 30 days before the application due date **Hyperlink:** (RFA-AI-15-020) **Type** RO1
(RFA-AI-15-021) R21

**Application Due Date:** RO1: July 28, 2015, by 5:00 PM local time of applicant organization

**Purpose:** The NIH, in collaboration with the Office of the Global AIDS Coordinator (OGAC) is soliciting applications for implementation science research that will inform delivery and scale-up of efficacious interventions to improve HIV prevention, care, and treatment in Africa.

**Budget**: RO1: Application budgets are limited to $500,000 in direct costs. The maximum project 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. The total project period may not exceed 2 years.

**4. Title: Analyses of Human Datasets and Biospecimens to Characterize Aging-related Phenotypes Relationships to Circulating Polypeptides and Proteins that Reverse or Accelerate Aging Changes**

**Letter of Intent due date:** 30 days before the application due date **Hyperlink:** (RFA-AG-16-012) **Type:** RO1

**Application Due Date:** July 9, 2015, by 5:00 PM local time of applicant organization

**Purpose:** This Funding Opportunity Announcement (FOA) invites applications to analyze existing datasets and stored biospecimens from human cohorts (e.g., epidemiologic studies, clinical trials) to advance understanding of potential effects in humans of polypeptides and proteins whose circulating levels change with age, and for which experimental evidence indicates reversal or acceleration of aging changes. Proposed studies in response to this FOA should address potential relationships of any selected polypeptide or protein to multiple outcomes, in order to evaluate both potential beneficial and adverse effects.

**Budget**: Application budgets are limited to $400,000 direct costs per year. The maximum project period is 5 years.

**5. Title: Consortia for Innovative AIDS Research in Nonhuman Primates**

**Letter of Intent due date:** 30 days before the application due date **Hyperlink:** (RFA-AI-15-022) **Type:** UM1

**Application Due Date:** July 29, 2015, by 5:00 PM local time of applicant organization

**Purpose:** This Funding Opportunity Announcement (FOA) solicits applications that will study a vaccine shown to have protected at least a subset of Nonhuman Primates (NHP) from lethal Simian Immunodeficiency Virus (SIV) or Simian-Human Immunodeficiency Virus (SHIV) mucosal challenge. The goals of this program include providing support for: 1) establishment of a collaborative multidisciplinary research NHP Consortium that will primarily focus on elucidating the mechanism(s) whereby this protective vaccine has blocked initial infection or has prevented establishment of persistent systemic infection and 2) research focused on innovative approaches that include a vaccine (and/or other immune interventions) as part of strategies to eliminate SIV/SHIV proviral reservoirs or lead to sustained remission after discontinuation of highly active antiretroviral therapy (HAART) in NHP.

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

**6. Title: Building towards Statistically-Based Pharmaceutical Quality Standards**

**Letter of Intent due date:** May 15, 2015, by 11:59 PM Eastern Time. **Hyperlink:** (RFA-FD-15-031) **Type:** UO1

**Application Due Date:** July 7, 2015, by 11:59 PM Eastern Time.

**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: $200,000 YR 02: $200,000 YR 03: $200,000. The maximum project period is three (3) years.

**7. Title: Data Concepts and Terminology Standards for the Support of Human Drug Development and Evaluation**

**Letter of Intent due date:** 30 days before the application due date **Hyperlink:** (RFA-FD-15-033) **Type** U24

**Application Due Date:** July 17, 2015, by 11:59 PM Eastern Time.

**Purpose:** The FDA Center for Drug Evaluation and Research is encouraging applications for projects to expedite development of data concepts and terminology standards, as well as assessments or evaluations of standards for use to support human drug development and evaluation. The primary objective is to support the development of non-proprietary, consensus-based, data standards for use in regulatory data for human drugs and biologics, while ensuring interoperability between clinical research and healthcare standards. Projects may focus on standards development, evaluation, or focus on a particular challenge area related to general clinical and nonclinical study data, specific therapeutic areas, as well as other sections of the regulatory submission (e.g., quality / Chemistry, Manufacturing, and Controls (CMC).

**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) for each year of support: YR 01: $225,000 YR 02: $225,000.The maximum project period is 2 years.

**8. Title: Developing the Therapeutic Potential of the Endocannabinoid System for Pain Treatment**

**Letter of Intent due date:** N/A **Hyperlink:** (PA-15-188) **Type** RO1

**Application Due Date:** Standard dates apply, by 5:00 PM local time of applicant organization: 5 June, 5 Oct, 5 Feb
Standard AIDS dates apply by 5:00 PM local time of applicant organization: 7 Sep, 7 Jan, May

**Purpose:** The purpose of this Funding Opportunity Announcement (FOA) is to support projects that will elucidate the therapeutic potential of the cannabinoids and endocannabinoid system in the development of mechanism-based therapies for pain.

**Budget**: Application budgets are not limited, but need to reflect the actual needs of the proposed project. The maximum period is 4 years. Applications with a project period less than 4 years are encouraged where feasible.

**9. Title: Immune System Plasticity in the Pathogenesis and Treatment of Complex Dental, Oral, and Craniofacial Diseases**

**Letter of Intent due date:** **Hyperlink:** (PAR-15-192) **Type** RO1
(PAR-15-193) R21

**Application Due Date:** Standard dates apply, by 5:00 PM local time of applicant organization RO1: 5 June, 5 Oct, 5 Feb
R21: 16 Jun, 16 Oct, 16 feb
Standard AIDS dates apply, by 5:00 PM local time of applicant organization: 7 Sep, 7 Jan, May

**Purpose:** The purpose of this Funding Opportunity Announcement (FOA) is to encourage research projects to elucidate the role of immune system plasticity in health and in the pathogenesis of dental, oral, and craniofacial diseases. The goal is to advance knowledge of the immunological basis of dental, oral, and craniofacial diseases, and to develop tools and technologies for precise modulation of the immune system to restore or maintain health. The expectation is that new knowledge derived from this research will facilitate development of novel immunomodulatory therapies to prevent disease onset or reverse disease progression.

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

**10. Title: NeuroNEXT Infrastructure Resource Access**

**Letter of Intent due date:** N/A **Hyperlink:** (PAR-15-195) **Type**

**Application Due Date:** Applications are accepted by continuous receipt, by 5:00 PM local time of applicant organization. Council Round: May Receipt Window: November 13 - March 12 Council Round: October Receipt Window: March 13 - July 12 Council Round: January Receipt Window: July 13 - November 12

**Purpose:** This FOA encourages applications for exploratory clinical trials of investigational agents (drugs, biologics, surgical therapies or devices) that may contribute to the justification for and provide the data required for designing a future trial, for biomarker validation studies, or for proof of mechanism clinical studies. Diseases chosen for study should be based on the NINDS' strategic plan and clinical research interests (www.ninds.nih.gov/funding/areas/index.htm). Successful applicants will be given access to the NeuroNEXT infrastructure. Following peer review, NINDS will prioritize and order trials that are given access to the NeuroNEXT infrastructure. The NeuroNEXT Clinical Coordinating Center (CCC) will work with the successful applicant to efficiently implement the proposed study. The NeuroNEXT Data Coordinating Center (DCC) will provide statistical and data management support. The NeuroNEXT clinical sites will provide recruitment/retention support as well as on-site implementation of the clinical protocol. Applicants do not need to be part of the existing NeuroNEXT infrastructure.

**Budget**: Not applicable, funds are not awarded via this X01.

**11. Title: Development and Application of Case Control Analysis for Generic Drugs**

**Letter of Intent due date:** May 22, 2015. **Hyperlink:** (RFA-FD-15-027) **Type** UO1

**Application Due Date:** July 2, 2015, by 11:59 PM Eastern Time.

**Purpose:** The project purpose is to develop case control analysis methods that can be used in the analysis of post-market data related to generic drug substitution.

**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: $200,000 YR 02: $200,000 YR 03: $200,000. The maximum project period is three (3) years.

**12. Title: Studies at Periviable Gestation**

**Letter of Intent due date:** 30 days prior to the application due date **Hyperlink:** (PA-15-200) **Type** RO1
(PA-15-198) R21
(PA-15-199) RO3

**Application Due Date:** Standard dates apply, by 5:00 PM local time of applicant organization RO1: 5 June, 5 Oct, 5 Feb
R21 & RO3: 16 Jun, 16 Oct, 16 Feb
Standard AIDS dates apply, by 5:00 PM local time of applicant organization: 7 Sep, 7 Jan, May

**Purpose:** The goals of this Funding Opportunity Announcement (FOA) are to focus on projects that will provide an evidence base to guide therapies and treatment at periviable gestational age for both mothers and their infants.

**Budget**: **RO1:** Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project 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. **RO3:** Direct costs are limited to $100,000 direct costs over the 2-year period, with no more than $50,000 in direct costs allowed in a single year

**13. Title: Pilot Health Services and Economic Research on the Treatment of Drug, Alcohol, and Tobacco Abuse**

**Letter of Intent due date:** N/A **Hyperlink:** (PA-15-250) **Type** R34

**Application Due Date:** Standard dates apply, by 5:00 PM local time of applicant organization 16 Jun, 16 Oct, 16 Feb
Standard AIDS dates apply, by 5:00 PM local time of applicant organization: 7 Sep, 7 Jan, May

**Purpose:** The purpose of this Funding Opportunity Announcement (FOA) is to encourage pilot and preliminary research in preparation for larger-scale services research effectiveness trials. Relevant trials may test a wide range of approaches, including interventions, practices, and policies, designed to optimize access to, and the quality, effectiveness, affordability and utilization of drug, tobacco, or alcohol use disorder treatments and related services, as well as services for comorbid medical and mental disorder conditions. Relevant approaches may include both those that are novel, and those that are commonly used in practice but lack an evidence base. This FOA provides resources for assessing the feasibility, acceptability, and utility of these approaches.

**Budget**: Direct costs are limited to $450,000 over the 3-year R34 project period, with no more than $225,000 in direct costs allowed in any single year.

**14. Title:** **Health Services and Economic Research on the Prevention and Treatment of Drug, Alcohol, and Tobacco Abuse**

**Letter of Intent due date:** N/A

**Hyperlink:** (PA-15-251) **Type** RO1
(PA-15-253) R21
(PA-15-252) RO3

**Application Due Date:** Standard dates apply, by 5:00 PM local time of applicant organization RO1: 5 June, 5 Oct, 5 Feb
R21 & RO3: 16 Jun, 16 Oct, 16 Feb
Standard AIDS dates apply, by 5:00 PM local time of applicant organization: 7 Sep, 7 Jan, May

**Purpose:** This Funding Opportunity Announcement (FOA) encourages grant applications to conduct rigorous health services and economic research to maximize the delivery of efficient, high-quality drug, tobacco, and alcohol prevention, treatment, and recovery support services. Examples of such research include: (1) clinical quality improvement; (2) quality improvement in services organization and management; (3) implementation research; (4) economic and cost studies; and (5) development or improvement of research methodology, analytic approaches, and measurement instrumentation used in the study of drug, alcohol, and tobacco prevention, treatment, and recovery services.

**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: 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. RO3: Budgets for direct costs of up to $50,000 per year may be requested. The maximum project period is 2 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).

**R25 – NIH Education Projects**: used in a wide variety of ways to promote an appreciation for and interest in biomedical research, provide additional training in specific areas, and/or to develop ways to disseminate scientific discovery into public health and community applications.

**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.

**R34 – Research Projects Planning Grant:** To provide support for the initial development of a clinical trial or research project, including the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design or experimental research designs and other essential elements of the study or project, such as the protocol, recruitment strategies, procedure manuals and collection of feasibility data.

**G11 Extramural Associate Research Development Award (EARDA) :** G11 Extramural Associate Research Development Award (EARDA) To provide funds to institutions eligible to participate in the NIH Extramural Associates Program for establishing or enhancing an office of sponsored research and for other research infrastructure needs.

**Complete Glossary and acronym list of NIH Terms**

NIH National Institutes of Health
*Turning Discovery Into Health*