NIH funding opportunities

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

- **Request for Information (RFI): Optimizing Funding Policies and Other Strategies to Improve the Impact and Sustainability of Biomedical Research (NOT-OD-15-084)**
- **Publication of the Revised NIH Grants Policy Statement (Rev. 3/31/2015) (NOT-OD-15-087)**
- **Notice of Availability of Additional Marijuana Strains through NIDA's Drug Supply Program (NOT-DA-15-064)**
- **Notice To Announce Continued Funding and Updated Research Objectives for PAS-13-031 "Stimulating Hematology Investigation: New Endeavors (SHINE) (R01)" (NOT-DK-15-011)**
- **Request for Information (RFI) on the Proposed Funding Priorities for Neuroscience Research, Input on High Impact and Cross-Cutting Opportunities (NIH Neuroscience Blueprint) (NOT-NS-15-020)**

1. Title: Oral Immune System Plasticity in Chronic HIV Infection Under Treatment and Oral Co-Infections

Letter of Intent due date: September 29, 2015 **Hyperlink:** (RFA-DE-16-002) **Type:** RO1

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

Purpose: This FOA solicits research projects that study the mechanisms of oral immune system plasticity relevant to chronic HIV infection and oral coinfections. In this context, we encourage studies on reversal of immune activation, residual inflammation, immune reconstitution inflammatory syndrome (IRIS), and microbial and by-product translocation. These conditions occur in persons chronically infected with HIV who are treated with combination antiretroviral therapy (cART) and who also experience oral opportunistic infections. The ultimate goals of this FOA are: 1) to gain knowledge regarding the pathogenesis and persistence of these oral conditions; and 2) to guide the development of novel oral immune modulatory therapies that will aid in re-building the oral immune system to reverse these diseases, mitigate their progression, prevent their occurrence, and eliminate persistence of residual HIV and other oral pathogens in reservoirs.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The total project period for an application submitted in response to this FOA may not exceed five years.

2. Title: Lifespan Human Connectome Project: Baby Connectome

Letter of Intent due date: August 3, 2015 **Hyperlink:** (RFA-MH-16-160) **Type:** UO1

Application Due Date: September 3, 2015, by 5:00 PM local time of applicant organization

Purpose: This FOA is issued as an initiative of the NIH Blueprint for Neuroscience Research. The Neuroscience Blueprint is a collaborative framework through which 15 NIH Institutes, Centers and Offices jointly support neuroscience-related research, with the aim of accelerating discoveries and reducing the burden of nervous system disorders (for further information, see http://neuroscienceblueprint.nih.gov/). The Neuroscience Blueprint is supporting a Lifespan Human Connectome Project (L-HCP) to extend the Human Connectome Project (HCP) (http://www.neuroscienceblueprint.nih.gov/connectome) to map connectivity in the developing, adult, and aging human brain. The goal of this FOA is to solicit grant applications that propose to extend the experimental protocols developed through the HCP to children in the 0-5 year old age range to investigate the structural and functional changes that occur in the brain during typical development. Related FOAs solicit applications that apply the HCP protocols to the 5-21 year old age range and to middle age and elderly adults to explore changes that occur during normal aging.

Budget: Application budgets are limited to $2,700,000 direct costs over all years of the award. The maximum project period is four years.

3. Title: HIV Vaccine Research and Design (HIVRAD) Program

Letter of Intent due date: 30 days prior to the application due date. **Hyperlink:** (PAR-15-164) **Type** PO1

Application Due Date: July 15, 2015; July 15, 2016; July 14, 2017 , by 5:00 PM local time of applicant organization.

Purpose: The purpose of this Funding Opportunity Announcement (FOA) is to support multi-component, multi-disciplinary projects that address important scientific questions relevant to AIDS prophylactic vaccine discovery research. Extensive modeling of vaccine concepts in non-human primates may be included.

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 period is 5 years.

4. Title: Exploratory Clinical Trials of Novel Interventions for Mental Disorders

Letter of Intent due date: 30 days before the application due date **Hyperlink:** (RFA-MH-16-400) **Type:** R33
(RFA-MH-16-405) R21/R33

Application Due Date: June 15, 2015; October 14, 2015; February 17, 2016; June 15, 2016; October 14, 2016,, by 5:00 PM local time of applicant organization

Purpose: The purpose of this Funding Opportunity Announcement (FOA) is to support the efficient pilot testing of novel interventions for mental disorders in adults and children through an experimental therapeutics approach. Under this FOA, trials must be designed so that results, whether positive or negative, will provide information of high scientific utility and will support "go/no-go" decisions about further development or testing of the intervention. Studies of novel interventions include, but are not limited to behavioral, pharmacological, biologics-based, cognitive, device-based, interpersonal, physiological, or combined approaches. Support will be provided for testing and validating the intervention's ability to affect a specified target, and for relating the change in target to functional or clinical effects. Ultimately, this funding mechanism is intended to speed the translation of emerging basic science findings of mechanisms and processes underlying mental disorders into novel interventions that can be efficiently tested for their promise in restoring function and reducing symptoms for those living with mental disorders

Budget: **R33** - 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, which may not exceed 3 years.

R21/R33 - The combined budget for direct costs for the R21 phase may not exceed $275,000. The budget for the R33 phase is 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 period of the combined R21 and R33 phases is 5 years, with up to 2 years for the R21 phase and up to 3 years for the R33 phase. Applications with a project period less than 5 years are encouraged where feasible.

5. Title: Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions

Letter of Intent due date: 30 days before the application due date **Hyperlink:** (RFA-MH-16-410) **Type:** R34

Application Due Date: June 15, 2015; October 14, 2015; February 17, 2016; June 15, 2016; October 14, 2016, by 5:00 PM local time of applicant organization.

Purpose: The purpose of this FOA is to encourage pilot research consistent with NIMH's priorities for: 1) effectiveness research on preventive and therapeutic interventions with previously demonstrated efficacy, for use with broader target populations or for use in community practice settings, and 2) research on the development and preliminary testing of innovative services interventions. Applications should provide resources for evaluating the feasibility, tolerability, acceptability and safety of approaches to improve mental health or functional outcomes, or modify risk factors, and for obtaining the preliminary data needed as a pre-requisite to a larger-scale intervention trial (e.g., comparative effectiveness study, practical trial) or large-scale services study. In this pilot phase of effectiveness research, NIMH places highest priority on approaches that can be justified in terms of their potential to substantially impact practice and public health and approaches that are empirically grounded. Adaptations or augmentations of efficacious interventions should only be undertaken if there is an empirical rationale for the adaptation target and for the corresponding mechanism by which the adapted intervention or augmentation is expected to substantially enhance outcomes. This FOA is intended to support pilot effectiveness trials that are designed to explicitly address whether the intervention engages the target/mechanism that is presumed to underlie the intervention effects.

Budget: Direct costs are limited to $450,000 over the R34 project period, with no more than $225,000 in direct costs allowed in any single year. The total project period for an application submitted in response to this funding opportunity may not exceed three years.

6. Title: Clinical Trials to Test the Effectiveness of Treatment, Preventive and Services Interventions (Collaborative)

Letter of Intent due date: 30 days before the application due date **Hyperlink:** (RFA-MH-16-415) **Type:** RO1

Application Due Date: June 15, 2015; October 14, 2015; February 17, 2016; June 15, 2016; October 14, 2016, by 5:00 PM local time of applicant organization.

Purpose: This FOA seeks to support investigator-initiated clinical trials to establish the effectiveness of interventions and to test hypotheses regarding moderators, mediators, and mechanisms of action of these interventions. This FOA supports clinical trials designed to test the therapeutic value of treatment and preventive interventions for which there is already evidence of efficacy, for use in community and practice settings. Applications might include research to evaluate the effectiveness or increase the clinical impact of pharmacologic, somatic, psychosocial (psychotherapeutic, behavioral), device -based, rehabilitative and combination interventions to prevent or treat mental illness. This FOA also supports clinical trials to test patient-, provider-, organizational-, or systems -level services interventions to improve service access, engagement, quality, coordination, or delivery, with the goal of improved outcomes at the individual and population level. The intervention research covered under this announcement is explicitly focused on practice-relevant questions. This FOA should be used when two or more sites are needed to complete the study. Accordingly, the collaborating studies share a specific protocol across the sites and are organized as such in order to increase sample size, accelerate recruitment, or increase sample diversity and representation. Each site has its own Program Director/Principal Investigator and the program provides a mechanism for cross-site coordination, quality control, database management, statistical analysis, and reporting.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years; however, applicants are strongly encouraged to limit their proposed project period to 3-4 years

7. Title: Clinical Trials to Test the Effectiveness of Treatment, Preventive and Services Interventions

Letter of Intent due date: 30 days before the application due date **Hyperlink:** (RFA-MH-16-420) **Type** RO1

Application Due Date: June 15, 2015; October 14, 2015; February 17, 2016; June 15, 2016; October 14, 2016, by 5:00 PM local time of applicant organization

Purpose: This FOA seeks to support investigator-initiated clinical trials to establish the effectiveness of interventions and to test hypotheses regarding moderators, mediators, and mechanisms of action of these interventions. This FOA supports clinical trials designed to test the therapeutic value of treatment and preventive interventions for which there is already evidence of efficacy, for use in community and practice settings. Applications might include research to evaluate the effectiveness or increase the clinical impact of pharmacologic, somatic, psychosocial (psychotherapeutic, behavioral), device-based, rehabilitative and combination interventions to prevent or treat mental illness. This FOA also supports clinical trials to test patient-, provider-, organizational-, or systems -level services interventions to improve service access, engagement, quality, coordination, or delivery, with the goal of improved outcomes at the individual and population level. The intervention research covered under this announcement is explicitly focused on practice-relevant questions.

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; however, applicants are strongly encouraged to limit their proposed project period to 3-4 years

8. Title: Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders

Letter of Intent due date: 30 days before the application due date **Hyperlink:** (RFA-MH-16-425) **Type** RO1

Application Due Date: June 15, 2015; October 14, 2015; February 17, 2016; June 15, 2016; October 14, 2016, by 5:00 PM local time of applicant organization.

Purpose: The purpose of this FOA is to support confirmatory efficacy testing of non-pharmacological therapeutic and preventive interventions for mental disorders in adults and children through an experimental therapeutics approach. Under this FOA, trials must be designed so that results, whether positive or negative, will provide information of high scientific utility and will support "go/no-go" decisions about further development, effectiveness testing, or dissemination of the intervention. Intervention studies include, but are not limited to behavioral, cognitive, interpersonal, and device-based approaches, or a combination thereof. Interventions appropriate for efficacy testing must be based on a compelling scientific rationale, previous demonstration that the intervention engages and alters the hypothesized mechanism of action, a preliminary efficacy signal, and must address an unmet therapeutic need. Support will be provided for a trial of the intervention's efficacy that includes measurement of the hypothesized mechanism of action and the relationship between change in the mechanism and change in functional or clinical effects. Ultimately, this FOA is intended to support a sufficiently- powered efficacy trial to determine the intervention's potential for significant clinical benefit.

Budget: **RO1** - 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; however, applicants are strongly encouraged to limit their proposed project period to 3 or 4 years.

9. Title: Secondary Analyses in Obesity, Diabetes and Digestive and Kidney Diseases

Letter of Intent due date: **Hyperlink:** (PA-15-169) **Type** R21

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

Purpose: This FOA encourages R21 applications that propose to conduct secondary analyses of existing data sets relevant to diabetes and selected endocrine and metabolic diseases including thyroid, parathyroid and Cushing's diseases and acromegaly; and genetic metabolic disease including cystic fibrosis, lysosomal storage diseases, and disorders of the urea cycle, amino acid metabolism and metal transport where the focus is on peripheral metabolism or organ function; obesity, liver diseases, alimentary GI tract diseases and nutrition; kidney, urologic, and hematologic diseases. The goal of this program is to facilitate research that explores innovative hypotheses through the use of existing data sets.

Budget: Direct costs are limited to $275,000 over an R21 two-year period, with no more than $200,000 in direct costs allowed in any single year. Application budgets need to reflect the actual needs of the proposed project.

10. Title: Diet and Physical Activity Assessment Methodology

Letter of Intent due date: 30 days prior to the application due date **Hyperlink:** (PAR-15-170) **Type** RO1
(PAR-15-171) R21

Application Due Date: For new applications: October 5, 2015; June 5, 2016; February 5, 2017; October 5, 2017; and June 5, 2018 (alternating standard R01 receipt dates).

Purpose: This Funding Opportunity FOA encourages innovative research to enhance the quality of measurements of dietary intake and physical activity. Applications submitted under this FOA are encouraged to include development of: novel assessment approaches; better methods to evaluate instruments; assessment tools for culturally diverse populations or various age groups, including children and older adults; improved technology or applications of existing technology; statistical methods/modeling to improve assessment and/or to correct for measurement errors or biases; methods to investigate the multidimensionality of diet and physical activity behavior through pattern analysis; or integrated measurement of diet and physical activity along with the environmental context of such behaviors.

Budget: RO1 - Application budgets are not limited but need to reflect the actual needs of the proposed project. The total project period may not exceed five years. R21- Direct costs are limited to $275,000 over a two-year period excluding consortium F&A costs, with no more than $200,000 in direct costs allowed in any single year.

11. Title: **Alzheimer's Drug-Development Program**

Letter of Intent due date: 30 days prior to the application due date **Hyperlink:** (PAR-15-174) **Type** UO1

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

Purpose: The goal of this FOA is to provide funding support for the pre-clinical and early stage clinical (Phase I) development of small-molecule and biologic therapeutic agents that prevent Alzheimer's disease (AD), slow its progression or treat its cognitive and behavioral symptoms. Participants in this program will receive funding for therapy development activities such as medicinal chemistry, pharmacokinetics (PK), Absorption, Distribution, Metabolism, Excretion, Toxicology (ADMET), efficacy in animal models, formulation development, chemical synthesis under Good Manufacturing Practices (GMP), Investigational New Drug (IND) enabling studies and initial Phase I clinical testing. This program does not support research on basic mechanisms of disease, development of biomarkers, devices, non-pharmacological interventions (e.g., exercise, diet, cognitive training), repurposed drugs and combinations therapies or, discovery activities such as high throughput screening and hit optimization.

Budget: Application budgets are limited to $1,000,000 in direct costs per year and need to reflect the actual needs of the proposed project. For Early Stage projects, the project period is limited to five years. For Late Stage projects, the project period is limited to three years.

12. Title: **Phenotypic and Functional Studies on FOXO3 Human Longevity Variants to Inform Potential Therapeutic Target Identification Research**

Letter of Intent due date: 30 days prior to the application due date **Hyperlink:** (PAR-15-175) **Type** RO1

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

Purpose: The focus of this FOA is on in vivo human studies, and in vitro studies on human cells or tissues, aimed at potential identification of therapeutic targets or and/or testing of interventions for healthy aging. Potential therapeutic targets include FOXO3 itself and upstream and downstream regulators in pathways mediated by FOXO3. The range of research areas of interest in this FOA includes studies that: 1) examine in vivo phenotypic effects of human FOXO3 variants, and/or 2) elucidate effects of these variants on cellular functions and the pathways that mediate them, and/or 3) identify and evaluate candidate therapeutic targets (e.g., target validation studies, testing of candidate compounds) for potential interventions based on FOXO3 functional pathways. Projects involving whole genome sequencing of new or existing cohorts are outside the scope of this FOA. However, targeted resequencing on a limited sample set in an existing cohort could be supported by this FOA.

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.

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.

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

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