NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 11 Feb 2019 (#5)

[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** or **www.sun.ac.za/RDSfunding** (current & archive).*

Confirm your intent to apply ASAP, but not later than 60 days before the submission date.

***Contact: RGMO Pre-Awards** cdevries@sun.ac.za*

Important Notices & News

Potential applicants often speculate that an R21 award is easier to get. However FY 2015 at NIAID, is the only year listed in which the R21 success rate was higher than the R01-equivalent success rate. So if you're deciding which activity code to use for an investigator-initiated application, the scope of your project (e.g., costs and time) and whether you have sufficient preliminary data to support an R01 should determine which mechanism you use, rather than past success rates. FY 2018 Application and Award Totals in the NIH Data Book

Success Rates (%)	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**
R01-Equivalent NIAID (NIH)	19.1 (18)	19.2 (19)	23.1 (20)	19.6 (19)	22.8 (19)
R21 NIAID (NIH)	17.9 (14)	20.9 (14)	22.9 (15)	16.0 (14)	21.5
Total NIH	20	20	20	20	20

Number of Awards: NIAID received more applications in FY 2018 than ever before, slightly more than in FY 2017. Within that total, the R21 application count increased while the R01-equivalent application count decreased. NIAID is receiving fewer R01-equivalent renewal applications.

Award Counts	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**
R01-Equivalent NIAID (NIH)	468 (5 066)	515 (5 375)	640 (5 874)	571 (5 775)	648
R21 NIAID (NIH)	405 (2 013)	502 (2 067)	573 (2 219)	408 (1 826)	565
Renewal R01-Equivalent NIAID	359	365	307	290	271

Award Average size (US$ 1000's)	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**
R01-Equivalent NIH	443	449	476	487	534
R21 NIH	220	221	221	222	

Paylines listed below for **established** investigators for R01 and R21 grant applications over the last five years. Note that the R01 paylines are calculated as percentiles while the R21 paylines are determined as overall impact scores, as explained at Understand Paylines and Percentiles. ***NIAID sets a separate payline for new and early-stage investigators, usually four percentage points higher than the general R01 payline to make it easier for new investigators to get an award.***

Paylines	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**
R01 as percentiles NIAID	9	12	13	11	13
R21 & R03 overall impact scores NIAID	23	30	30	28	32

- **Updates to NIH Policy for identifying Early Stage Investigators (ESI) Application Status** (NOT-OD-19-072). NIH remains strongly committed to the Next Generation Researcher Initiative (NGRI) policy to fund more early career investigators and to enhance biomedical research workforce diversity.
- Notice of Special Interest in Supporting **Administrative Supplements for Fetal Alcohol Spectrum Disorders** (FASD) (NOT-AA-19-009)
- Request for Information (RFI): Immunologic Assays for Identifying Correlates of Protection (COP) Against **Congenital Cytomegalovirus Transmission and/or Disease** (NOT-AI-19-035)
- Request for Information (RFI): Input on In-depth **Stem Cell Characterization** (NOT-HL-19-679)

1. Computational Models of Immunity (U01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** RFA-AI-19-011 **Type: U01**
Application Due Date: June 10, 2019. Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) solicits applications developing computational models of immunity that advance understanding of the mechanisms required to induce and/or maintain protective immunity to infectious pathogens, other than HIV, and/or vaccines against such pathogens. The main goal of this FOA is to advance development and application of computational models of immunity that are refined through iterative immunological experimentation to validate and improve the utility and robustness of the computational models. Another goal of this FOA is to make the computational models and data developed under this initiative readily available to the broader research community for further refinement or direct use in biological experimentation. This program will also support workshops and symposia to foster the use of computational models of immunity by the broader research community.
Budget: NIAID intends to commit $4.0 million in FY 2020 to fund 3 - 4 awards. Application budgets are limited to $750,000 direct costs per year and 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.

2. Research to Advance HBV Cure: HIV/HBV Co-Infection and HBV Mono-infection (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** PAS-19-097 **Type: R01**
Application Due Date: Standard dates & Standard AIDS dates Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to invite applications for support of innovative basic, translational, and clinical research to identify and address the challenges to achieving hepatitis B virus (HBV) cure in the presence or absence of human immunodeficiency virus (HIV).
Budget: NIH intends to fund an estimate of 3-5 awards, corresponding to a total of $4.1M, for fiscal year 2020, 2021, 2022. Future year amounts will depend on annual appropriations. 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. Secondary Analysis of Existing Datasets for Advancing Infectious Disease Research (R21 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** PA-19-068 **Type: R21**
Application Due Date: Standard dates Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to support projects that utilize open-access data, alone or in combination with other datasets, to address knowledge gaps in basic and/or clinical research in infectious diseases.
Budget: Direct costs are limited to $275,000 over a two-year project period, with no more than $200,000 in direct costs allowed in any single year. The maximum project period is 2 years.

4. Urgent Competitive Revision to Existing NIH Grants and Cooperative Agreements (Urgent Supplement - Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** PA-18-935 **Type:**
Application Due Date: Open dates may vary by awarding IC. See Urgent Guide Notices for applicable Application Due Dates. Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The National Institutes of Health (NIH) hereby notify Principal Investigators holding specific types of NIH research grants, listed in the full Funding Opportunity Announcement (FOA) that funds may be available for competitive revisions to meet immediate needs to help address a specific public health crisis in a timely manner, but that were unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted. Applications for Urgent Competitive Revisions will be routed directly to the NIH awarding component listed on the NoA of the most recent parent award. Only applications submitted in response to an Urgent Guide Notice published by an IC will be allowed to apply to this FOA.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The parent award must be active when the application is submitted. The project and budget periods must be within the currently approved project period for the existing parent award.

5. Functional RNA Modifications Environment and Disease (FRAMED) (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-ES-19-001) **Type: R01**
(RFA-ES-19-002) **R21**

Application Due Date: May 16, 2019. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: Chemical modifications of protein, DNA and RNA nucleoside moieties play critical roles in regulating gene expression. Emerging evidence suggests RNA modifications have substantive roles in multiple basic biological processes. Epitranscriptomics can be defined as the aggregate suite of functional biochemical modifications to the transcriptome within a cell. Recent studies in yeast, Drosophila, rodent and human models demonstrate that stressors can induce RNA modifications, with specific reprogramming of some regulatory RNAs. The NIEHS seeks to solicit innovative, mechanistic research applications that are focused on how environmental exposures are associated and involved with the functional activities of RNA modifications and pathways that may be modified or misregulated, associated with adverse health outcomes and/or be useful as biomarkers of exposure and/or exposure induced pathologies. The study of functional chemical RNA modification has identified important emerging roles in cellular regulation and gene expression. However, the impact of environmental exposures on functional RNA modifications has been relatively understudied and may present a new mechanism for enhanced understanding the relationships between exposures and the development of complex human diseases. The NIEHS will use the **R01** mechanism to support research using approaches that incorporate principles of toxicology with RNA modification biological and/or chemical expertise and utilizes state of the art technologies. **R21** applications propose innovative, high risk, high reward research addressing how environmental exposures impact this layer of cellular regulation.

Budget: **R01** - NIEHS intends to commit $2,000,000 in FY 2020 to fund 5 awards. Application budgets are limited to $250,000 per year in Direct Costs. The scope of the proposed project should determine the project period. The maximum project period is 5 years. **R21** - NIEHS intends to commit $1,000,000 in FY2020 to fund 4 awards. Application budgets are limited to $150,000 Direct Costs per year. The scope of the proposed project should determine the project period. The maximum project period is 2 years.

6. Bioequivalence of Topical Products: Bioequivalence Considerations for Ungual, Scalp, Vaginal, Anal or Rectal Dosage Forms (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-FD-19-008) **Type: U01**

Application Due Date: April 11, 2019, by 11:59 PM Eastern Time.

Funding Opportunity Announcement: The purpose of this funding opportunity is to support the research and development necessary to elucidate specific considerations that may be uniquely relevant to evaluating the bioequivalence (BE) of ungual (nail), scalp, vaginal, or rectal topical drug products. A specific emphasis of this funding opportunity involves the development of in vitro or ex vivo, comparative product characterization-based BE approaches.

Budget: FDA/Center for Drug Evaluation and Research intends to fund up to $250,000 for fiscal year 2019 in support of this research program. 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: $250,000 and YR 02: $250,000.

7. Bioequivalence of Topical Products: Elucidating the Sensorial and Functional Characteristics of Compositionally Different Topical Formulations (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-FD-19-009) **Type: U01**

Application Due Date: April 11, 2019, by 11:59 PM Eastern Time.

Funding Opportunity Announcement: The purpose of this funding opportunity is to support research relevant to topical semisolid drug products that will help elucidate the relationship between a product's quality attributes and its functional properties. A specific purpose is to elucidate how characterizations of the arrangement of matter, including rheological characterizations (e.g., texture analysis, tribology) may correlate with and/or be predictive of sensorial differences perceived by human subjects (or patients). Upon the successful completion of this research, it should be possible to predict, based upon product quality characterizations, whether test and reference products that may be compositionally different are likely to have a comparable look and feel, including comparable perceptions of grittiness, silky-smoothness, and cooling sensation.

Budget: FDA/Center for Drug Evaluation and Research intends to fund up to $500,000 for fiscal year 2019 in support of this research program. It is anticipated that up to 1 award will be made, not to exceed $500,000 in total costs (direct plus indirect), per year. The scope of the proposed project should determine the project period. The maximum project period is two (2) years.

8. Secondary Data Analysis to Examine Long-Term and/or Potential Cross-Over Effects of Prevention Interventions: What are the Benefits for Preventing Mental Health Disorders? (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-20-110) **Type: R01**

Application Due Date: Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this funding opportunity announcement (FOA) is to encourage research to integrate/harmonize existing data sets from preventive intervention trials implemented early in life to: 1) examine risk and protective factors relevant to later mental health outcomes in childhood, adolescence and young adulthood; and 2) determine whether preventive interventions delivered earlier in life have long-term effects, and/or cross-over effects (e.g., unanticipated beneficial effects), on important mental health outcomes, including serious mental illness (e.g., depression, anxiety, suicide ideation and behaviors, psychosis behaviors).

Budget: NIMH intends to commit $3 million total costs in FY 2020 to fund 4-6 awards. NCCIH intends to commit $500,000 total costs in FY 2020 to fund 1 award. Application budgets are limited to $500,000 direct costs (not including consortium F&A) in any project year and 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 3 years.

9. Bioequivalence of Topical Products: Evaluating the Cutaneous Pharmacokinetics of Topical Drug Products Using Pharmacokinetic Tomography (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-FD-19-010) **Type: U01**
Application Due Date: April 11, 2019, by 11:59 PM Eastern Time.
Funding Opportunity Announcement: The purpose of this funding opportunity is to support the research and development necessary to advance non-invasive (e.g., quantitative tomography-based) technologies, including the development of apparatus, methods, study designs, and methods of data analysis, to characterize and compare the rate and extent to which a topically applied drug becomes available at or near a site of action within the skin. The expectation is that the funded work will produce an accurate, sensitive and reproducible approach that rapidly measures the (relative) amount of drug present in the skin at a series of depths below the skin surface, which can be utilized to monitor the cutaneous pharmacokinetics (PK) of the drug at selected depths (e.g., in the epidermis and dermis) by repeated, serial measurements over time. The intent is to support the eventual development of an alternative, scientifically valid, cutaneous PK-based approach that can be used to efficiently demonstrate the bioequivalence (BE) of topical products.
Budget: FDA/Center for Drug Evaluation and Research intends to fund up to $500,000 for fiscal year 2019 in support of this research program. It is anticipated that up to 1 award will be made. 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: $250,000; YR 03: $250,000; YR 04: $250,000; YR 05: $250,000.. The maximum project period is five (5) years.

10. Refinement and Testing of Interventions to Sustain ADHD Treatment Effects Across Settings and Developmental Transitions (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-20-100) **Type: R34**
Application Due Date: May 1, 2019 and November 15, 2019. Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: NIMH seeks applications for pilot projects to evaluate the preliminary effectiveness of augmented or modified interventions designed to promote sustained improvement in attention-deficit/hyperactivity disorder (ADHD) symptoms and functional impairments across settings and transitions in children, adolescents, and young adults. An emphasis is placed on trials that go beyond seeking incremental gains in intervention effects, and instead take a theory-driven, empirical approach to applying modifications that will have a significant and enduring impact on functioning. In this pilot phase of effectiveness research, the trial should be designed to evaluate the feasibility, tolerability, acceptability, safety, and potential effectiveness of the approach; to address whether the intervention engages the target mechanism(s) presumed to underlie the intervention effects; and to obtain necessary preliminary data as a pre-requisite to a larger-scale, definitive effectiveness trial.
Budget: NIMH intends to commit $1.4M in direct costs in FY2020 to fund 5-6 awards. 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.

11. Biology of Bladder Cancer (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-19-183) **Type: R01**
(PAR-19-184) **R21**
Application Due Date: Standard dates Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) encourages applications investigating the biology and underlying mechanisms of bladder cancer. Bladder cancer is a significant health problem both in the United States and globally. Because of the high incidence and frequent tumor recurrence, bladder cancer exacts an outsized medical burden. While recent progress has been made in the molecular profiling of bladder cancers and identification of mutated genes, relatively little is known regarding the molecular mechanisms driving initiation, progression, and malignancy of bladder cancer. Furthermore, our understanding of biological processes of the normal bladder at the molecular, cell and organ levels is limited. Fundamental knowledge of how molecular and cellular functions of the bladder are altered in cancer will aid our understanding of bladder cancer biology and interventions. Applications that involve multidisciplinary teams and use clinical specimens or investigate both normal and cancer processes are encouraged.
Budget: R01 - 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 a single year.

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