

Faculty of Medicine and Health Sciences: Research Development and Support 27 Feb 2019 (#6)

[Click on blue <u>hyperlink</u> 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

- Findings of Research Misconduct (NOT-OD-19-080)
- Update to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials (NOT-OD-19-083)
- NIH Now Updates ESI Status in eRA Commons Automatically: If you are an early-stage investigator (ESI), submit an application, and then update or request an extension of your ESI status, NIH will automatically update the ESI status of your application within eRA Commons.
- How To Submit RPPRs With Inclusion Enrollment Data: Find instructions for preparing a Research
 Performance Progress Report with inclusion enrollment data following technical updates from eRA Commons.
- Request for Information for a Review of the NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding Document (NOT-OD-19-078)
- Revised Guidance on Protecting Life in Global Health Assistance (NOT-OD-19-079)

1. Enhancing Regulatory Science for the Risk Based Quality Assessment of Complex Products - Clinical Trials Optional

Letter of Intent: 30 days prior to the application due date

Hyperlink: (RFA-FD-19-011)

Application Due Date: April 22, 2019 by 11:59 PM Eastern Time.

Funding Opportunity Announcement: The purpose of this program is to support research activities that expand the knowledge base related to complex products and formulation development, analysis, and manufacturing control to advance risk-based quality assessment of new and generic drug products. We will also consider biological products relevant to CDER (e.g., monoclonal antibodies and therapeutic proteins) for this announcement.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for two (2) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA/CDER intends to fund up to \$2,000,000, for fiscal year 2019 in support of this grant program. It is anticipated that up to two awards will be made, not to exceed \$1,000,000 in total costs (direct plus indirect), per award. The scope of the proposed project should determine the project period. The maximum project period is three (3) years.

2. Tobacco Regulatory Science (Clinical Trial Optional)

Letter of Intent: 60 days prior to the application due date.

Hyperlink: (RFA-OD-19-019)

Type: R01

Application Due Date: July 19, 2019, February 13, 2020, July 17, 2020,. Apply by 5:00 PM local time of applicant organization. **Funding Opportunity Announcement:** The purpose of this Funding Opportunity Announcement (FOA) is to invite R01 applications to support biomedical and behavioral research that will provide scientific data to inform regulation of tobacco products to protect public health. Research Projects must address the research priorities related to the regulatory authority of the Food and Drug Administration (FDA) Center for Tobacco Products (CTP). The awards under this FOA will be administered by NIH using funds that have been made available through FDA CTP and the Family Smoking Prevention and Tobacco Control Act (P.L. 111-31). Research results from this FOA are expected to generate findings and data that are directly relevant in informing the FDA's regulation of the manufacture, distribution, and marketing of tobacco products to protect public health.

Budget: NIH, via support from the FDA Center for Tobacco products (CTP), intends to fund up to 8 R01s, corresponding to a total of up to \$4 million, for fiscal year 2020. Future year amounts will depend on availability of funds. Application budgets are limited to \$300,000 in direct cost per year. The scope of the proposed project should determine the project period. The maximum project period is 3 years.

3. Development of Standard Core Clinical Outcomes Assessments (COAs) and Endpoints (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date

Hyperlink: (RFA-FD-19-006)

Type: UG3/UH3

Application Due Date: May 31, 2019, by 11:59 PM Eastern Time.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to solicit applications for UG3/UH3 cooperative agreements to support the development of a publicly available core set(s) of COAs and their related endpoints for specific disease indications. The UG3/UH3 Phase Innovation Award Cooperative Agreement involves 2 phases. The UG3 phase will provide funding for 1 to 2 years to conduct planning activities. The UH3 phase will provide funding for 3 to 4 years to projects that successfully complete the planning activities and reach the projected milestones set in the UG3 phase. UH3 phase awards will be awarded after administrative review of eligible UG3 phase awards that have met the scientific milestone and feasibility requirements necessary for UH3 phase implementation. The number of awards is dependent on the availability of funds. The UG3/UH3 application must be submitted as a single application, and applicants should note specific instructions for each phase in this FOA. The total award project period will not exceed 5 years.

Budget: FDA/CDER intends to commit up to \$4,200,000 total for fiscal year 2019 to fund up to three (3) awards in support of this grant 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): UG3 (up to 2 years): Combined years: up to \$1,400,000 total costs/per award. It is up to the applicant to determine the number of years and budget for the UG3 phase. The application should provide justification for the number of years and budget split among the years if the UG3 phase is anticipated to take more than 1 year. UH3 (up to 4 years): Combined years: up to \$2,700,000 total costs/award. It is up to the applicant to determine the number years and budget for the UH4 phase. The application should provide justification for the number of years for the UH3 phase and budget split among the years. The scope of the proposed project should determine the project period. The UG3 phase is limited to up to two years and the UH3 phase can request up to four years of support. The total project period for an application submitted in response to this FOA may not exceed five (5) years.

4. Ruth L. Kirschstein National Research Service Award (NRSA) Individual Senior Fellowship (Parent F33)

Letter of Intent: 30 days prior to the application due date

Hyperlink: (PA-19-187)

Application Due Date: Standard dates & Standard AIDS dates Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The National Institutes of Health (NIH) awards senior individual research training fellowships to experienced scientists who wish to make major changes in the direction of their research careers or who wish to broaden their scientific background by acquiring new research capabilities as independent investigators in research fields relevant to the missions of participating NIH Institutes and Centers. This Funding Opportunity Announcement (FOA) does not allow applicants to propose to lead an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial, but does allow applicants to propose research experience in a clinical trial led by a sponsor or co-sponsor.

Type: F33

Budget: Award budgets are composed of stipends, tuition and fees, and institutional allowance, as described below. Individuals may receive up to 5 years of aggregate Kirschstein-NRSA support at the predoctoral level (up to 6 years for dual degree training, e.g., MD/PhD), and up to 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from institutional training grants (e.g., T32) and an individual fellowship award. Senior fellowship (F33) support may be requested for a period of up to 2 years. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research and clinical training experiences. See https://researchtraining.nih.gov/resources/policy-notices. Senior Fellows. The amount of the Kirschstein-NRSA stipend to be paid must be commensurate with the base salary or remuneration that the individual receiving the award would have been paid by the institution with which he or she has permanent affiliation on the issue date of the fellowship award. In no case shall the stipend award exceed the current Kirschstein-NRSA stipend limit set by NIH. The level of Kirschstein-NRSA support will take into account concurrent salary support provided by the institution and the policy of the sponsoring institution. NIH support does not provide fringe benefits for senior fellows. Fellowship awards will contribute to the combined cost of tuition and fees at the rate in place at the time of award. See https://researchtraining.nih.gov/resources/policy-notices. The application should request a Kirschstein-NRSA institutional allowance to help defray the cost of fellowship expenses such as health insurance, research supplies, equipment, books, and travel to scientific meetings. See https://researchtraining.nih.gov/resources/policy-notices. Fellowship awards do not include a separate reimbursement for indirect costs (also known as Facilities & Administrative [F&A] Costs). Instead, costs for administering fellowships are covered by the Institutional Allowance. See https://researchtraining.nih.gov/resources/policy-notices

5. Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32)

Letter of Intent: 30 days prior to the application due date Hyperlink: (PA-19-188) Type: F32

Application Due Date: Standard dates & Standard AIDS dates Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32) is to support research training of highly promising postdoctoral candidates who have the potential to become productive, independent investigators in scientific health-related research fields relevant to the missions of the participating NIH Institutes and Centers. Applications are expected to incorporate exceptional mentorship. This Funding Opportunity Announcement (FOA) does not allow applicants to propose to lead an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial, but does allow applicants to propose research experience in a clinical trial led by a sponsor or co-sponsor.

Budget: Award budgets are composed of stipends, tuition and fees, and institutional allowance, as described below. Individuals may receive up to 5 years of aggregate Kirschstein-NRSA support at the predoctoral level (up to 6 years for dual degree training, e.g., MD/PhD), and up to 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from institutional training grants (e.g., T32) and an individual fellowship award. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research and clinical training experiences.

6. Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-19-195)

Application Due Date: Standard dates & Standard AIDS dates Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31) award is to enable promising predoctoral students to obtain individualized, mentored research training from outstanding faculty sponsors while conducting dissertation research in scientific health-related fields relevant to the missions of the participating NIH Institutes and Centers. The proposed mentored research training must reflect the applicant's dissertation research project and is expected to clearly enhance the individual's potential to develop into a productive, independent research scientist. This Funding Opportunity Announcement (FOA) does not allow applicants to propose to lead an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial, but does allow applicants to propose research experience in a clinical trial led by a sponsor or co-sponsor.

Budget: Award budgets are composed of stipends, tuition and fees, and institutional allowance, as described below. Individuals may receive up to 5 years of aggregate Kirschstein-NRSA support at the predoctoral level (up to 6 years for dual degree training, e.g., MD/PhD), and up to 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from institutional training grants (e.g., T32) and an individual fellowship award. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research and clinical training experiences. Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage.

7. Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31)

Letter of Intent: 30 days prior to the application due date

Hyperlink: (PA-19-196) **Type: F31**

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 Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research award is to enhance the diversity of the health-related research workforce by supporting the research training of predoctoral students from diverse backgrounds including those from groups that are underrepresented in the biomedical, behavioral, or clinical research workforce. Through this award program, promising predoctoral students will obtain individualized, mentored research training from outstanding faculty sponsors while conducting well-defined research projects in scientific health-related fields relevant to the missions of the participating NIH Institutes and Centers. The proposed mentored research training is expected to clearly enhance the individual's potential to develop into a productive, independent research scientist. This Funding Opportunity Announcement (FOA) does not allow applicants to propose to lead an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial, but does allow applicants to propose research experience in a clinical trial led by a sponsor or co-sponsor.

Budget: Award budgets are composed of stipends, tuition and fees, and institutional allowance, as described below. Individuals may receive up to 5 years of aggregate Kirschstein-NRSA support at the predoctoral level (up to 6 years for dual degree training, e.g., MD/PhD), and up to 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from institutional training grants (e.g., T32) and an individual fellowship award. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research and clinical training experiences. See https://researchtraining.nih.gov/resources/policy-notices. Fellowship awards will contribute to the combined cost of tuition and fees at the rate in place at the time of award. See https://researchtraining.nih.gov/resources/policy-notices. The application should request a Kirschstein-NRSA institutional allowance to help defray the cost of fellowship expenses such as health insurance, research supplies, equipment, books, and travel to scientific meetings. See https://researchtraining.nih.gov/resources/policy-notices. Fellowship awards do not include a separate reimbursement for indirect costs (also known as Facilities & Administrative [F&A] Costs). Instead, costs for administering fellowships are covered by the Institutional Allowance. See https://researchtraining.nih.gov/resources/policy-notices. Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the NIH Guide for Grants and Contracts, and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage.

8. Pilot Services Research Grants Not Involving Clinical Trials (R34 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date

Hyperlink: (PAR-19-189)

Type: R34

Type: F31

Application Due Date: March 28, 2019 with standard receipt dates thereafter by 5:00 PM local time of applicant organization <u>Standard dates</u> Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this funding announcement is to encourage pilot research that is not an immediate precursor to testing a service intervention but is consistent with NIMH priorities for services research. While NIMH now requires use of an experimental therapeutics model for all intervention studies, there is recognition that some mission-relevant areas of services research do not involve clinical trials. These areas include:

- 1) studies to identify mutable factors that impact access, continuity, utilization, quality, value, outcomes, including disparities in outcomes, or scalability of mental health services, which may serve as targets in future intervention development
- 2) development and testing of new research tools, measures, or methods
- 3) testing the feasibility of integrating existing data sets to understand factors affecting access, quality or outcomes of care
- 4) pilot work on the learning mental health care system model as a means to enable practical studies of the value and effectiveness of services and treatments

Studies focused on the development or preliminary testing of services interventions should be submitted under RFA-MH-18-706.

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 one year. The total project period for an application submitted in response to this funding opportunity may not exceed three years.

9. Advancing Post-Market Surveillance of High-Risk Facilities and Products through Signal detection, Data analysis, and the Review of the State of Quality (U01) Clinical Trial Optional

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-19-190) **Type:** U01

Application Due Date: May 1, 2019, by 11:59 PM Eastern Time, April 4, 2020, by 11:59 PM Eastern Time, April 5, 2021, by 11:59 PM Eastern Time. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this program is to advance comprehensive quality surveillance and provide the state of quality for all regulated sites and products. Using predictive analytics, data mining, and other quantitative tools, this research program will expand the knowledge base related to site and product quality, especially for high-risk foreign facilities and their products Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for TWO (2) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA/CDER intends to fund up to \$1,500,000, for fiscal year 2019 in support of this grant program. It is anticipated that up to two (2) awards will be made, not to exceed \$750,000.00 in total costs (direct plus indirect), per award, per year.

10. Microbial-based Cancer Therapy -Bugs as Drugs (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date

Hyperlink: (PAR-19-193)

Type: R01

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

Funding Opportunity Announcement: The overall purpose of this funding opportunity announcement (FOA) is to stimulate the development of novel microbial-based cancer therapies, especially for conditions where conventional cancer therapies are inadequate, such as poorly vascularized, hypoxic, solid tumors, dormant or slowly dividing cells resistant to current interventions, and brain tumors. Utilizing bacteria, archaebacteria, bacteriophages and other non-virus microorganisms, this initiative will support research projects designed to study the underlying mechanisms of the complex interactions between microorganisms, tumor, and immune system. The FOA also aims to support research into the use of microorganisms as delivery vehicles for cancer treatment and to complement or synergize with current therapies. This FOA will accept basic mechanistic and preclinical studies in cell culture and animal models in accordance with the state of the science. Applicants applying to this FOA are encouraged to address both the microbial and the tumor aspects of microbialbased cancer therapy. Complex microbial-tumor interactions are best addressed with a team approach. The purpose of this FOA is to encourage basic or applied, multidisciplinary research collaborations between investigators from areas relevant to microbial-based cancer therapy, such as microbiology, oncology, immunology, and cellular and molecular cancer biology. The proposed projects should be state of the art and aim to advance pre-clinical development of novel microbial-based anticancer therapeutic agents, or study the complex biology involved in the interplay of microbe-tumor-immune system. An application may propose design-directed, developmental, discovery-driven, or hypothesis-driven research, and should apply an integrative approach to increase our understanding of biological, or translational aspects of microbial-based anticancer therapeutic agents. The R21 FOA is intended to encourage exploratory projects that are at an early conceptual stage feasibility study (inception through preliminary development) to demonstrate core functional capabilities of the proposed approach. The proposed projects may involve considerable risk and should be aimed at producing breakthroughs in microbial-based cancer therapy.

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 any single year.

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