NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 06 Apr 2016 (#10)

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*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) Pre-Awards** (Dr Christa Coetsee cdevries@sun.ac.za) **as soon as possible to inform of your intent to apply and then confirm at least 30 days before the submission date**. The NIH grant is submitted institutionally. **All final application documents MUST reach the RGMO seven (7) workdays before NIH application due date.***

Important notices

- **Restructured and Streamlined Application Guides and Supplemental Instructions Available for Applications Due Dates On or After May 25, 2016 (NOT-OD-16-084)**
- **Clarifications and Consolidated Biosketch Instructions and Format Pages Available for Applications with Due Dates On or After May 25, 2016 (NOT-OD-16-080)**
- **Reminder: NIH & AHRQ Grant Application Changes for Due Dates On or After May 25, 2016 (NOT-OD-16-081)**
- **Reissue of parent grants:**
  - **NIH Research Project Grant (Parent R01) (PA-16-160)**
  - **NIH Exploratory/Developmental Research Grant Program (Parent R21) (PA-16-161)**
  - **NIH Small Research Grant Program (Parent R03) (PA-16-162)**
- **Learn more about NIH Parent Announcements for unsolicited or investigator-initiated applications.**
- **Notice of Pre-Application Webinar for RFA-HL-17-003 "T4 Translation Research Capacity Building Initiative in Low Income Countries (TREIN) (U24) (NOT-HL-16-306)**
- **Revision of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) to Streamline Review Process for Human Gene Transfer Protocols (NOT-OD-16-076)**
- **Reporting Instructions for Publications Supported by Shared Resources in Research Performance Progress Reports (RPPR) and Renewal Applications (NOT-OD-16-079)**
- **Notice of Clarification of NOT-DA-16-015 "Request for Information (RFI): Strategies for Non-Invasive Imaging of HIV Reservoirs" (NOT-DA-16-020)**

1. The Early Detection Research Network: Biomarker Developmental Laboratories

Letter of Intent due date: 30 days prior to the application due date **Hyperlink:** (RFA-CA-16-009) **Type: UO1**

Application Due Date: May 23, 2016. Apply by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: The purpose of this Funding Opportunity Announcement (FOA) is to solicit organ-specific applications for Biomarker Developmental Laboratories (BDLs), one of the four scientific units of the recently funded Early Detection Research Network (EDRN). The EDRN is a national infrastructure funded to discover, develop, and validate biomarkers for risk assessment, detection, and molecular diagnosis and prognosis of early cancer. BDLs are responsible for the discovery, development, characterization, and testing of new, or the refinement of existing, biomarkers and biomarker assays for risk assessment, detection, and molecular diagnosis and prognosis of cancers. The existing BDLs are primarily focused on ovary and gastrointestinal cancers. The proposed BDLs (to be supported under this FOA) must be focused on cancers of the breast, prostate and other genitourinary organs, and lung. In addition, cancers with rapidly rising incidence rates, e.g., endometrial, hepatocellular, kidney, thyroid, oropharyngeal cancers, and/or cancers with unique etiology, e.g., mesothelioma, will be responsive. The other three scientific units of the continuing EDRN program are: the Biomarker Reference Laboratories (BRLs), which serve as Network resources for clinical and laboratory validation of biomarkers; the Clinical Validation Centers (CVCs), which conduct clinical research on the validation of biomarkers and serve as resource centers for the EDRN by participating in collaborative biomarker validation studies with EDRN BDLs and BRLs; and the Data Management and Coordinating Center (DMCC), which support statistical and computational analyses, informatics infrastructure, study design, coordination and support of EDRN-sponsored biomarker validation studies, and the coordination of Network-wide meetings and conferences.

Budget: A budget of up to $400,000 per year in direct costs may be requested. The indicated budget limit may be appropriate for larger projects involving multiple laboratories (and possibly multiple PDs/PIs). Smaller projects (e.g., involving one PD/PI and a single laboratory) are expected not to exceed $250,000 per year in direct costs. Application budgets need to reflect the actual needs of the proposed project. An applicant may request a project period of up to 5 years.

2. Oral Immune System Plasticity in Chronic HIV Infection Under Treatment and Oral Co-Infections

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-DE-17-006) **Type: R01**

Application Due Date: July 25, 2016. Apply by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

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 scope of the proposed project should determine the project period. The maximum period is 5 year.

3. Assessment of Intersubject Variability in Small Airway Delivery with Oral Inhalation Drug Products

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-FD-16-024) **Type: U01**

Application Due Date: May 16, 2016, by 11:59 PM Eastern Time apply. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: FDA's CDER is seeking depositional data obtained with a computational modeling approach for small airway delivery to adults with orally inhaled drug products (OIDPs) that are indicated for management of asthma. Possible sources of inter-subject variability include lengths and diameters of various airway segments, heterogeneous or homogeneous constriction, and inhalation patterns. An expected outcome is regional deposition data for reference listed drugs that can indicate whether or not the drug product targets small airways in asthmatic patients and the key product attributes that affects the deposition.

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

4. Implementing Population Pharmacokinetic Modeling Algorithm in Physiologically-based Pharmacokinetic Models to Allow Parameter Estimation at Individual Data Level

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-FD-16-026) **Type:** U01

Application Due Date: May 16, 2016, by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: The purpose of this project is to develop and implement a robust optimization algorithm that can be used to perform population-based statistical analysis in complex and computationally intensive physiologically based pharmacokinetic (PBPK) models so that knowledge of parameter distributions in the population(s) of interest can be derived. The models developed will be used to generate predictions that can inform bioequivalence assessments and regulatory decisions relating to generic drug development.

Budget: FDA/CDER intends to fund up to $500,000, for fiscal year 2016 in support of this grant program. It is anticipated that up to two awards will be made, not to exceed $250,000 in total costs (direct plus indirect), per award. 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; YR 02: $250,000. The scope of the proposed project should determine the project period. The maximum project period is 2 years.

5. Development of Animal Models and Related Biological Materials for Research

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (PA-16-141) **Type: R21**

Application Due Date: Standard dates and Standard AIDS dates apply. Apply by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: This funding opportunity announcement (FOA) encourages highly innovative research to develop, characterize or improve animal models and related biological materials for human health and disease or to improve diagnosis and control of diseases that might interfere with animal use for biomedical research purposes. The proposed project must fall within the categorical interests of two or more NIH institutions/centers. Applications to develop models that relate strictly to a specific disease or category of research will not be accepted and should be proposed to the appropriate categorical Institute or Center of the NIH.

Budget: No more than $200,000 direct costs may be requested in any single year. The combined budget may not exceed $275,000 direct costs for the two year project period. The total project period may not exceed 2 years.

6. Using the NIMH Research Domain Criteria (RDoC) Approach to Understand Psychosis

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (PAR-16-135) (PAR-16-136) **Type: R21 R01**

Application Due Date: Standard dates apply. Apply by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: NIMH seeks applications which propose research studies that will use the NIMH's Research Domain Criteria (RDoC) framework to advance scientific understanding of neurobehavioral mechanisms related to psychotic symptoms (hallucinations, delusions, disorganized behavior, and thought disorder).

Budget: 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. **R01** - Application budgets are limited to $500,000 annual direct costs. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

7. International AIDS Education and Training Center

Letter of Intent due date: **Hyperlink:** HRSA-16-174 **Type: Cooperative Agreement**

Application Due Date: May 23, 2016 Apply by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: This announcement solicits applications for the International AIDS Education and Training Center (IAETC) program. The IAETC program is aligned with HRSA's mission to improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs. The IAETC program will implement activities globally that are in alignment with the President's Emergency Plan for AIDS Relief (PEPFAR) 3.0 and its focus on reaching the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 global treatment targets and, ultimately, PEPFAR's plan to reach epidemic control of HIV. The mechanism will also reflect a continued emphasis on impact, data, sustainability, and accountability through all aspects of the global HIV response. The goal of this program is to improve health outcomes for people living with HIV (PLWH) along the HIV treatment cascade by building sustainable health systems, including a global workforce with the right skills, mix, and distribution to respond to HIV and other population health priorities in countries in sub-Saharan Africa, the Caribbean, Central Asia, Eastern Europe, Latin America, and other countries with significant or increasing HIV and other infectious disease incidence rates. The program objectives are to: Identify, pilot, evaluate, and scale up new approaches to effective and efficient HIV service delivery through technical assistance, consultation and training; Strengthen evidence-based comprehensive prevention approaches by targeting key populations including adolescent girls and young women; and Improve diagnosis, linkage, treatment, retention and viral suppression through training, consultation, and technical assistance.

Budget: Expected Number of Awards is 2. Estimated Total Program Funding $45,000,000

8. Evaluation of Aberrant Observations and Their Impact on Bioequivalence Assessment

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-FD-16-018) **Type: UO1**

Application Due Date: June 03, 2016, by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: Aberrant observations in a bioequivalence study with pharmacokinetic endpoints may impact the estimation of residual variability, within-subject variability of the test and reference products, and potentially the bioequivalence conclusion. The purpose of this study is to evaluate and compare different quantitative methods for their capability in defining aberrant observations in bioequivalence studies with different study design features. Study results will advance regulatory science by improving the detection and understanding of aberrant observations and may help generic companies to evaluate the quality and in vivo performance of their proposed products.

Budget: It is anticipated that up to 3 awards will be made, not to exceed $200,000 in total costs (direct plus indirect), per award.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. The scope of the proposed project should determine the project period. The maximum project period is two (2) years

9. Integrating Supersaturation-precipitation Mechanisms in Mechanistic Oral Absorption Models for Predicting In-vivo Performance of Associated Formulations

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-FD-16-025) **Type: U01**

Application Due Date: June 03, 2016, by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: The objectives of this project are to: 1) integrate in vivo supersaturation-precipitation mechanisms into mechanism-based oral absorption models for poorly water-soluble drugs formulated into supersaturable systems, and 2) to establish a mechanism-based in vitro-in vivo correlation (IVIVC) for these drug products.

Budget: It is anticipated that up to 2 awards will be made, not to exceed $250,000 in total costs (direct plus indirect), per award. 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/award; YR 02: $250,000/award.

10. Bioequivalence of Topical Products: Comparing Dermal Pharmacokinetics by Microdialysis or Microperfusion Techniques

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-FD-16-028) **Type: U01**

Application Due Date: June 03, 2016, by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: The purpose of this funding opportunity is to support the research and development necessary to advance microdialysis or open flow microperfusion methods, study designs, and analyses to directly measure the rate and extent to which a topically applied compound becomes available in the dermis, 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 measures the amount of drug present in the dermis over time.

Budget: It is anticipated that up to two (2) awards will be made, not to exceed $500,000 in total costs (direct plus indirect), per award. Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect): YR 01: $500,000; YR 02: $500,000; YR 03: $500,000. The scope of the proposed project should determine the project period. The maximum project period is three (3) years.

11. Role of Astrocytes and Astrocytic Networks in Drug Abuse

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (PA-16-144) **Type: R01**
(PA-16-145) **R21**

Application Due Date: Standard dates and Standard AIDS dates apply, by 5:00 PM local time of applicant organizationApplicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submis sion process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: Despite continuing advances in understanding astrocyte function within the CNS, little is known as to the impact of drugs of abuse on the structural organization and functional information encoded within astrocytic networks. The purpose of this Funding Opportunity Announcement (FOA) is to encourage the submission of applications to examine the effects of drugs of abuse on the structural connectivity of astrocytic networks within the CNS, and the generation, processing and spatiotemporal control of activities within these networks.

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 -** Direct costs are limited to $275,000 for the total two-year period, with no more than $200,000 in direct costs allowed in any single year.

12. Population Health Interventions: Integrating Individual and Group Level Evidence

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (PA-16-146) **Type: R01**
(PA-16-147) **R21**

Application Due Date: Standard dates and Standard AIDS dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: To improve health and reduce the burden of disease, scientific research needs to be implemented at the population level in addition to the biological and clinical levels. The purpose of this funding opportunity announcement (FOA) is to support multilevel, transdisciplinary population health interventions that target underlying social, economic, and environmental conditions in an effort to improve health outcomes.

Budget: R01- 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. **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.

13. Discovery of the Genetic Basis of Childhood Cancers and of Structural Birth Defects: Gabriella Miller Kids First Pediatric Research Program

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (PAR-16-150) **Type: X01**

Application Due Date: June 17, 2016, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: As part of the Gabriella Miller Kids First Pediatric Research Program (Kids First), the NIH invites applications to use whole genome sequencing at a Kids First-supported sequencing center to elucidate the genetic contribution to childhood cancers, and to investigate the genetic etiology of structural birth defects. These data will become part of the Gabriella Miller Kids First Pediatric Data Resource (Kids First Data Resource) for the pediatric research community.

Budget: Not applicable; there are no funds associated with a resource access award.

14. Advances in Polycystic Kidney Disease

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (PA-16-159) **Type: R01**

Application Due Date: Standard dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: The purpose of this Funding Opportunity Announcement (FOA) is to increase investigator interest in basic and applied investigations of the etiology and pathogenesis of Polycystic Kidney Disease (PKD), in both its autosomal dominant and autosomal recessive forms. The ultimate aim is to facilitate PKD-related research studies, which will provide the basis for new therapeutic approaches.

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.

15. Prevention Innovation Program III (PIP)

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-AI-16-025) **Type: R01**

Application Due Date: August 3, 2016, by 5:00 PM local time of applicant organizationApplicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: The Prevention Innovation Program III (PIP) encourages research applications in Non-vaccine Biomedical Prevention (nBP) research. The PIP is intended to support high-risk/innovative research and development efforts to establish and maintain a sustainable pipeline for the prevention of HIV acquisition/transmission. The PIP will support: 1) discovery and development of novel and under-explored nBP candidates/strategies, 2) discovery and development of nBP drug delivery systems (DDS), 3) studies of the impact of nBP prevention products and DDS on genital and gastrointestinal (GI) mucosa function, 4) development of emerging technologies to support and facilitate nBP prevention product and DDS discovery and development, 5) development of age appropriate formulation strategies (AFS), and 6) development of Multipurpose Prevention Technologies (MPT) for prevention of HIV acquisition/transmission.

Budget: NIAID intends to commit $1.8 Million in FY 2017 to fund 2-3 awards. Application budgets are limited to $400,000 per year in direct costs. Applicants will submit a 4 year R01 application, and are required to identify a SINGLE Go/No-Go decision criterion to be achieved by the Year 2 progress report. Achievement of the stated goal (Go) will enable continuation of the R01 and advancement to years 3 and 4 of funding enabling a total of 4 years of support, while failure to achieve the stated goal (No-Go) will result in negotiation of a reduced budget for Year 3 and award close out.

16. Partnerships for Countermeasures against Select Pathogens

Letter of Intent due date: 30 days prior to the Application Due Date **Hyperlink:** (RFA-AI-16-034) **Type: R01**

Application Due Date: October 3, 2016, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: The purpose of this FOA is to solicit research applications for milestone-driven projects focused on preclinical development of lead candidate countermeasures (therapeutics, vaccines and related technologies, or diagnostics) against select NIAID Emerging Infectious Diseases/Pathogens. Applications must include a Product Development Strategy attachment and demonstrate substantive investment by at least one industrial participant.

Budget: NIAID intends to commit $10 million in FY 2017 to fund 10-15 awards. Budgets for direct costs of up to $750,000 per year may be requested. Applicants may also request up to an additional $300,000 in the first year of the award for major equipment to ensure that research objectives can be met and biohazards can be contained, totalling $1,050,000 direct costs. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

17. Revision Applications to R01 Awards for Research on the NCI's Provocative Questions

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-CA-16-010) **Type: R01**

Application Due Date: June 28, 2016; October 28, 2016, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: This FOA invites revision applications from investigators with active NIH R01 research grants. These revision applications are expected to focus on research related to one of the 12 of the NCI's Provocative Questions (PQs) published for new applications in RFA-CA-15-008 and RFA-CA-15-009. This FOA encourages research that directly addresses PQs, including research that helps validate PQ research outcomes or adopt and disseminate PQ research results that impact cancer research and clinical care. Studies proposed in the revision applications must correspond to additional specific aims, expanding the scope of individual, already funded projects of the parent R01 award.

Budget: The NCI expects to commit up to $750,000 (total cost) in FY2017 to this FOA to fund up to 3 awards for both review rounds combined. The number of awards is contingent upon and the submission of a sufficient number of meritorious applications. The budget may not exceed $150,000 Direct Costs per year. Applicants may request support for up to two years, not to exceed the remaining number of years on the parent grant. The parent grant must be active when the application is submitted. If a no-cost extension is needed on the parent grant, it must be in place before the revision application is submitted.

18. Revision Applications to U01 Awards for Research on the NCI's Provocative Questions

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-CA-16-011) **Type: U01**

Application Due Date: June 28 2016; October 28, 2016, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: This FOA invites revision applications from investigators with active NCI U01 research project awards. These revision applications are expected to focus on research related to one of the 12 of the NCI's Provocative Questions (PQs) published for new applications in RFA-CA-15-008 and RFA-CA-15-009. This FOA encourages research that directly addresses PQs, including research that helps validate PQ research outcomes or adopt and disseminate PQ research results that impact cancer research and clinical care. Studies proposed in the revision applications must correspond to additional specific aims, expanding the scope of individual, already funded projects of the parent U01 award.

Budget: The NCI expects to commit up to $750,000 (total cost) in FY2017 to this FOA to fund up to 3 awards for both review rounds combined. The number of awards is contingent upon and the submission of a sufficient number of meritorious applications. The budget may not exceed $150,000 Direct Costs per year. Applicants may request support for up to two years, not to exceed the remaining number of years on the parent grant. The parent grant must be active when the application is submitted. If a no-cost extension is needed on the parent grant, it must be in place before the revision application is submitted.

19. Use of Imaging and Digital Image Analysis Software/s to Evaluate Transdermal Irritation and Non - inferiority of Generic Transdermal Products

Letter of Intent due date: April 15, 2016 **Hyperlink:** (RFA-FD-16-010) **Type: U01**

Application Due Date: May 31, 2016, by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: Use of "trained observers" for clinical evaluation of transdermal irritation has the potential for observer bias and variability in assessment since the various transdermal systems that are applied on subjects for such studies are usually visually dissimilar. Use of digital images and image analysis software/s has the potential to enhance consistency and reliability of the measurements compared to visual assessment. The purpose of this study is to help evaluate if digital imaging can be used to quantify transdermal irritation and for non-inferiority analysis of generic transdermal systems.

Budget: FDA/CDER intends to fund up to $250,000, for fiscal year 2016 in support of this grant program. It is anticipated that up to one (1) awards will be made, not to exceed $250,000 in total costs (direct plus indirect), per award. 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; YR 02: $250,000

20. Generic Drug Substitution in Special Populations

Letter of Intent due date: April 18, 2016 **Hyperlink:** (RFA-FD-16-011) **Type: U01**

Application Due Date: June 03, 2016, by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: The purpose of this study is to: 1) collect information on practice patterns in special populations to assess possible barriers to generic substitution ; 2) compare clinical practice (e.g., drug product manipulation prior to administration, co-administration with another food or drug) with labeled drug administration information in the assessed populations to identify factors that raise issues for safety and effectiveness with generic substitution; and 3) analyze the impact of product-level, patient-level, and provider-level factors on generic drug substitution. The outcome of this study will help identify research needs, support FDA's regulatory science efforts to monitor and ensure successful generic substitution, and provide evidence to assure the public on generic drug safety and effectiveness.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations, availability of funding and awardee performance. FDA/CDER intends to fund up to $400,000, for fiscal year 2016 in support of this grant program. It is anticipated that up to two (2) awards will be made, not to exceed $200,000 in total costs (direct plus indirect), per award, per year. 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. The maximum project period is two (2) years.

21. Bioequivalence of Topical Products: Comparing Epidermal Pharmacokinetics by Spectroscopic Imaging Techniques

Letter of Intent due date: N/A **Hyperlink:** (RFA-FD-16-029) **Type: U01**

Application Due Date: June 03, 2016 by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: The purpose of this funding opportunity is to support the research and development necessary to advance spectroscopic imaging technologies, methods, study designs, and analyses to non-invasively measure the rate and extent to which a topically applied compound becomes available in the epidermis, 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 measures the amount of drug present in the epidermis at each of a series of depths below the skin surface, which can be utilized to monitor epidermal pharmacokinetics by repeated measurements over time.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations, availability of funding and awardee performance. FDA/CDER intends to fund up to $500,000, for fiscal year 2016 in support of this grant program. It is anticipated that up to two (2) awards will be made, not to exceed $250,000 in total costs (direct plus indirect), per award. 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; YR 02: $250,000. The maximum project period is two (2) years

22. Adult Maturational Changes and Dysfunctions in Emotion Regulation

Letter of Intent due date: 30 days prior to the Application Due Date(s) **Hyperlink:** (RFA-MH-17-400) **Type: R21**
(RFA-MH-17-405) **R01**

Application Due Date: July 22, 2016, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.

Purpose: This funding opportunity announcement (FOA) invites applications for mechanistically oriented, exploratory and developmental research on how age- and sex-related changes in emotion processing develop over the adult life course and how these changes may interact with and inform the understanding of affective dysregulation in adult mental disorders and Alzheimer's disease. In particular, research is sought that will leverage the already established normative backdrop of generally improved emotion regulation with aging, as well as research that will expand this evidence base. One aim is to clarify the trajectories of change in emotion processing and linked neurobiological and neurobehavioral factors in aging adults who experience mood and anxiety disorders. Equally important aims are to advance understanding of the factors involved in normative maturational shifts in these processes and of sources of individual variation therein, and to clarify how such shifts (or lack thereof) may relate to irregularities in the integrative neural-behavioral mechanisms of affect regulation seen in these adult mental disorders and in Alzheimer's disease. It is anticipated that such studies may identify novel targets for mental health interventions or prevention efforts, or

provide clues as to which available intervention strategies might be optimally applied to normalize emotion dysregulation or to strengthen emotional resilience at different stages of the adult life cycle.
Budget: NIMH intends to commit $3.3 million and NIA $750,000 in FY 2017 so as, together, to fund approximately 8-12 awards in response to this and its companion R01 announcement. **R21 -** Direct costs are limited to $275,000 over the two-year project 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. The maximum project period is 2 years. **R01** -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.

23. NIH Research Project Grant

Letter of Intent due date: N/A **Hyperlink:** (PA-16-160) **Type: R01**
Application Due Date: Standard dates and Standard AIDS dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.
Purpose: The NIH Research Project Grant supports a discrete, specified, circumscribed project in areas representing the specific interests and competencies of the investigator(s). The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions.
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.

24. NIH Exploratory/Developmental Research Grant Program

Letter of Intent due date: N/A **Hyperlink:** (PA-16-161) **Type: R21**
Application Due Date: Standard dates and Standard AIDS dates apply, by 5:00 PM local time of applicant organization. local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.
Purpose: The NIH Exploratory/Developmental Grant supports exploratory and developmental research projects by providing support for the early and conceptual stages of these projects. These studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioral, or clinical research.
Budget: 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.

25. NIH Small Research Grant Program

Letter of Intent due date: N/A **Hyperlink:** (PA-16-162) **Type: R03**
Application Due Date: Standard dates and Standard AIDS dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.
Purpose: The NIH Small Research Grant Program supports small research projects that can be carried out in a short period of time with limited resources. This program supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology.
Budget: Application budgets are limited to $50,000 in direct costs per year. The total project period may not exceed two years.

26. NeuroNEXT Clinical Trials

Letter of Intent due date: N/A **Hyperlink:** (PAR-16-155) **Type: U01**
Application Due Date: August 2, 2016; December 6, 2016; April 4, 2017; August 3, 2017, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. ***Applicants should be aware that on-time submission means that an application is submitted error free*** (of both Grants.gov and eRA Commons errors) on the application due date.
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: Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum request cannot exceed 5 years but the actual funded project period is dependent on reaching specific milestones as described in this FOA.

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

D71 - International Research Training Planning Grant: To plan for the preparation of an application for a D43 international research training grant or for a U2R international research training cooperative agreement.

D43 - International Research Training Grants: To support research training programs for US and foreign professionals and students to strengthen global health research and international research collaboration.

DP1 – NIH Director's Pioneer Award (NDPA): To support individuals who have the potential to make extraordinary contributions to medical research. The NIH Director's Pioneer Award is not renewable.

DP3 – Institutional Training and Director Program Projects -Type 1 Diabetes Targeted Research Award: To support research tackling major challenges in type 1 diabetes and promoting new approaches to these challenges by scientific teams.

P20 – Research Program Projects and Centers -Exploratory Grant: To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

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).

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).

R03 – NIH Small Grant Program: limited funding for short period to support e.g. pilot / feasibility study, collection of preliminary data, secondary analysis of existing data, small-contained research projects, development of new research technology, etc.; normally for "new investigators"; not renewable; up to 2 years; budget generally <$50,000 (direct costs).

R21/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.

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.

R34 - Clinical Trial Planning Grant Program: To provide support for the initial development of a clinical trial, 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 and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

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.

U24 – Resource-Related Research Projects – Cooperative Agreements: To support research projects contributing to improvement of the capability of resources to serve biomedical research.

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.

UH2/UH3 – NIH Phase Innovation Awards Cooperative Agreement: 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.

U2R – International Research Training Cooperative Agreements: Cooperative agreement mechanism for D43 to support research training programs for US and foreign professionals and students to strengthen global health research and international research collaboration.

U19 - **Research Program-Cooperative Agreements:** supports a research program of multiple projects directed toward a specific major objective, basic theme or program goal, requiring a broadly based, multidisciplinary and often long-term approach. A cooperative agreement research program generally involves the organized efforts of large groups, members of which are conducting research projects designed to elucidate the various aspects of a specific objective.

Glossary of selected acronyms:

FOA Funding Opportunity Announcement

PA Program Announcements *(click on "PA" to search for further funding opportunities)*

RFA Request for Applications *(click on "RFA" to search for further funding opportunities)*

Complete Glossary and acronym list of NIH Terms