NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 26 Mar 2018 (#9)

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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.*

Confirm your intent to apply ASAP, but not later than 30 days before the submission date.

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

Important notices:

- **Can I increase my effort on a grant without increasing my salary and thus keep my budget the same?**
- **NIAID's Investigator-Initiated Clinical Trial Policies You should contact a program officer at least 10 weeks before the receipt date when applying to conduct an investigator-initiated clinical trial.**
- **Request for Information (RFI): Animal Care and Use in Research (NOT-OD-18-152)**

1. Can I increase my effort on a grant without increasing my salary and thus keep my budget the same

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-FD-18-010) **Type: *U01***
Application Due Date: May 19, 2018, by 11:59 PM ***Eastern Time***.
Funding Opportunity Announcement: The purpose of this funding opportunity is to support the research necessary to elucidate how systematic alterations to the qualitative (Q1) and/or quantitative (Q2) composition of topical formulations impacts their physical, structural, and functional properties. A key aspect of the research relates to understanding how the thermodynamic properties of a topical dosage form change as it undergoes metamorphosis during dose application and drying on the skin, how the drug's thermodynamic activity profile during the metamorphosis of the dosage form may compare between compositionally different (non-Q1 and/or non-Q2) topical formulations, and how these and other forces may modulate the rate and extent to which topically applied drugs may become available at or near their site(s) of action in the skin. Another key aspect of the research relates to identifying and understanding other potential failure modes for bioequivalence (BE) and/or therapeutic equivalence (TE) (e.g., differences in irritation potential) that may arise between compositionally different (non-Q1 and/or non-Q2) topical formulations.
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 four (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA/Center for Drug Evaluation and Research intends to fund up to $500,000 for fiscal year 2018 in support of this research program. It is anticipated that up to 2 awards will be made, not to exceed $250,000 in total costs (direct plus indirect), per year 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): $250,000 per year. The scope of the proposed project should determine the project period. The maximum project period is five (5) years.

2. Bioequivalence of Topical Products: Evaluating the Cutaneous Pharmacokinetics of Topical Drug Products Using Non-Invasive Techniques

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-FD-18-012) **Type: *U01***
Application Due Date: June 4, 2018, 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., spectroscopic/ imaging tomography) technologies, 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 measures the 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 or dermis) by repeated measurements over time. The ultimate intent is to support the eventual development of an alternative, scientifically valid, cutaneous PK-based approach to efficiently evaluate the bioequivalence (BE) of topical products in vivo in human subjects.
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 four (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA/Center for Drug Evaluation and Research intends to fund up to $500,000 for fiscal year 2018 in support of this research program. It is anticipated that up to 2 awards will be made, not to exceed $250,000 in total costs (direct plus indirect), per year per award. The scope of the proposed project should determine the project period. The maximum project period is five (5) years.

3. Computational fluid dynamics (CFD) and discrete element modeling (DEM) approach for predictions of dry powder inhaler (DPI) drug delivery

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-FD-18-014) **Type:**
Application Due Date: May 29, 2018, by 11:59 PM Eastern Time.
Funding Opportunity Announcement: Current product-specific bioequivalence (BE) guidance published by the Office of Generic Drugs for dry powder inhalers (DPIs) include in vitro testing recommendations for single actuation content and aerodynamic particle size distribution, as well as recommendations for a pharmacokinetic study and a pharmacodynamic or clinical endpoint study. Given the extensive nature of current DPI BE guidance, it is desirable that current in vitro testing for DPIs be more reflective of in vivo performance. Computational fluid dynamics (CFD) and discrete element modeling (DEM) have been used to predict dry powder aerosol behavior, including the effects of agglomeration and deagglomeration. The purpose of the study will be to develop a CFD-DEM model which can be used to evaluate the impact of various physicochemical properties and device performance properties on regional deposition, to identify potentially biorelevant ranges for these properties that may be useful for future BE recommendations.
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/Center for Drug Evaluation and Research intends to fund up to $380,000, for fiscal year 2018 in support of this grant program. It is anticipated that up to two awards will be made, not to exceed $190,000 in total costs (direct plus indirect), per award, per year in YR 01 and 02 and $20,000 in total costs (direct plus indirect), per award, per year in YR 03. The scope of the proposed project should determine the project period. The maximum project period is three (3) years.

4. Characterize skin physiology parameters utilized in dermal physiologically-based pharmacokinetic model development across different skin disease states

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-FD-18-017) **Type:** ***U01***
Application Due Date: May 29, 2018, by 11:59 PM Eastern Time.
Funding Opportunity Announcement: The purpose of this project is to identify skin physiology characteristics that differ between healthy and skin disease population groups and incorporate them into dermal physiologically-based pharmacokinetic models to improve their predictability. The models developed will be utilized to perform virtual bioequivalence assessments between brand name and generic drug products to inform regulatory decisions relating to the development of generic topical dermatological drug products and transdermal delivery systems.
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 up to one (1) additional year contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA/Center for Drug Evaluation and Research intends to fund up to $500,000, for fiscal year 2018 in support of this grant program. It is anticipated that up to two awards will be made, not to exceed $250,00 in total costs (direct plus indirect), per year, per award. The scope of the proposed project should determine the project period. The maximum project period is two (2) years.

5. Formulation drug product quality attributes in dermal physiologically-based pharmacokinetic models for topical dermatological drug products and transdermal delivery systems

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-FD-18-019) **Type:** ***U01***
Application Due Date: May 28 , 2018, by 11:59 PM Eastern Time.
Funding Opportunity Announcement: The purpose of this project is to incorporate drug product quality attributes into dermal physiologically-based pharmacokinetic models developed for dermatological topical dosage forms and transdermal delivery systems. The developed models will be utilized to identify drug-product specific critical quality attributes (model qualification) and perform virtual bioequivalence assessments between brand name and generic drug products to inform regulatory decisions relating to the development of dermatological drug 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 up to one (1) additional year contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA/Center for Drug Evaluation and Research intends to fund up to $500,000, for fiscal year 2018 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. The scope of the proposed project should determine the project period. The maximum project period is two (2) years.

6. International Bioethics Research Training Program

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-716) **Type:** ***D43***
Application Due Date: May 17, 2018. Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The overall goal of this initiative is to support the development of a sustainable critical mass of bioethics scholars in low and middle-income country (LMIC) research intensive institutions with the capabilities to conduct original empirical or conceptual ethics research that addresses challenging issues in health research and research policy in these countries as well as provide research ethics leadership to their institutions, governments and international research organizations. FIC will support LMIC-U.S. collaborative institutional bioethics doctoral and postdoctoral research training programs that incorporate didactic, mentored research and training components to prepare a number of individuals with ethics expertise for positions of scholarship and leadership in health research institutions in the LMIC. This FOA allows support of Trainees as the lead investigator of an independent clinical trial; or a separate ancillary study to an existing trial; or to gain research experience in a clinical trial led by another investigator, as part of their research and career development.
Budget: Applicants may request up to $230,000 direct costs per year. The total project period for an application submitted in response to this funding opportunity may not exceed 5 years.

7. Fogarty HIV Research Training Program for Low-and Middle-Income Country Institutions

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-717) **Type:** ***D43***

Application Due Date: August 23, 2018. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this FOA is to encourage applications for research training programs to strengthen the scientific capacity of institutions in low- and middle-income countries (LMICs) to conduct HIV research relevant to the evolving HIV epidemic in their country. This FOA can support training for a broad range of HIV research areas across HIV prevention, care and treatment including basic, epidemiologic, clinical, behavioral and social sciences, implementation, operations, health services, and health systems research. Cross-disciplinary and community-based research as well as HIV associated comorbidities and coinfections affecting the HIV epidemic will be supported under this FOA. An application should focus the proposed training program to strengthen research capacity in a defined HIV scientific area at a specific LMIC institution or at LMIC sites in an established HIV research network. This Funding Opportunity Announcement (FOA) allows appointment of Trainees proposing to serve as the lead investigator of an independent clinical trial; or proposing a separate ancillary study to an existing trial; or proposing to gain research experience in a clinical trial led by another investigator, as part of their research and career development.

Budget: Application budgets are limited to $280,000 direct costs per year exclusive of consortium indirect costs. The maximum project period is 5 years.

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

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