Deadline(s): NEW: Feb. 16; Jun. 16; Oct. 16; RESUBMISSION: Mar. 16, Jul. 16, Nov. 16 (non-renewable)
Anticipated Project Start Date(s): December 1; April 1; July 1
Budget: Direct Costs up to $275,000 over 2 year period; no more than $200,000 in a single year

The following checklist is for the NIH Exploratory Developmental Research Grant Program (parent R21), PA-13-303. This mechanism supports the development of new research activities in categorical program areas. The R21 activity code is intended to encourage 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. Preliminary data not required; however, some preliminary data in support of feasibility recommended. When applying for a program-specific R21, please make sure that you and your assigned Grants Officer review the guidelines thoroughly for any additional requirements and/or variations. Your Grants Officer will download the Grants.gov package, but you are responsible for providing the items below (Word or PDF format).

Formatting (from the SF_424 Guide):
Font: Arial (preferred), Helvetica, Palatino Linotype, or Georgia; 11 pt. font or larger; black ink only. The symbol font may be used to insert Greek letters or special characters.
Type density: no more than 6 lines per vertical inch and no more than 15 characters per inch.
Margins: minimum one-half inch
Spacing: space between paragraphs and headings in bold. Do not use headers/footers.
Title Length: The NIH limits project title character length to 200 characters, including spaces.

Scope
These are should be exploratory, novel studies that break new ground or extend previous discoveries toward new directions or applications.
High risk high reward studies that may lead to a breakthrough in a particular area, or result in novel techniques, agents, methodologies, models or applications that will impact biomedical, behavioral, or clinical research.
Projects should be distinct from those supported through the traditional R01 mechanism.

For additional information on the R21 application: http://grants1.nih.gov/grants/funding/r21.htm

PLEASE MAKE SURE THAT YOUR IC OF INTEREST SUPPORTS THE R21 MECHANISM BEFORE YOU SUBMIT.
IT IS ALSO RECOMMENDED THAT YOU CONTACT THE APPROPRIATE NIH PROGRAM OFFICER PRIOR TO PROPOSAL SUBMISSION IN ORDER TO ENSURE THE “BEST FIT”.

ITEMS REQUIRED BY THE NIH: for individual component detail, the page numbers (below) reference the SF 424 Guide.*

Research & Related Project Performance Site Locations: All project sites must be included

___ Abstract/Project Summary: 30 line maximum, self-contained description of the project which includes a statement of objectives and methods to be employed (not a summary of accomplishments). State the application’s broad, long-term objectives and specific aims, making reference to the mission of the agency. Will be public domain. p. I-76

___ Appendix (attachment) cannot be used to circumvent page limits. pp.I-144—I-145

___ Bibliography & References Cited: No page limit; list all authors in the sequence appearing in the publication. P. I-77

___ Biographical Sketch (attachment; 5 page limit for each Senior/Key personnel) Please note that there are new requirements for the NIH Biosketch. Go here for complete instructions: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html. Applications with non-compliant biosketches will be rejected by the NIH. pp. I-88—I-89

___ Budget Justification (attachment) List all personnel, effort, project role and contribution, no salary information. p. I-127**

___ Cover Letter (attachment) Optional, but encouraged if a particular institute or study section is desired. pp. I-64—I-65

___ Equipment: List of major equipment already available for project; list location and pertinent capabilities. p. I-78

___ Facilities & Other Resources: Identify and describe facilities to be used (lab, animal, computer, etc.). Describe how the scientific environment in which the research will be done contributes to the probability of success. pp. I-77—I-78

___ Human Subjects (if applicable: Protection of Human Subjects; Inclusion of Women & Minorities; Targeted/Planned Enrollment Table (form); Inclusion of Children) For complete, detailed instructions, see pp. I-135—I-136

___ Introduction (for resubmissions or revisions only) 1 page limit. p. I-131

___ Letters of Support (attachment) p. I-141
Pre-Award Proposal Checklist
NIH R21

_____Narrative (Public Relevance Statement): In 2 – 3 sentences, describe in language for lay audience the relevance of this research to public health. Will be public domain. p. I-77

_____Research Strategy (attachment) 6 page max; (a. significance, b. innovation, c. approach) For complete, detailed instructions, please see pp. I-133—I-134

_____Resource Sharing Plan (attachment) pp. I-142—I-143

_____Specific Aims (attachment) 1 page limit; concisely state the project goals and summarize expected outcome. p. I-132

_____Vertebrate Animals (attachment; if applicable) address five points as listed on pp. I-137—I-138

* For complete detailed instructions of each required component, it is recommended that you consult the SF_424 Guide. There may be variations from the guide, based on the Program Announcement. Your Grants Officer can help you with this.

**Although the Modular Budget does not require a detailed budget, a Banner-compliant budget is required before expenditure of awarded funds. MURC recommends that a detailed budget be prepared prior to submission. All budgets must be reviewed by the Grants Officer.

OTHER REQUIRED ITEMS:

_____Authorization to Submit (ATS) Form: The ATS form must be routed for administrative approval and signature prior to proposal submission.

_____Significant Financial Interest Disclosure (SFID): In accordance with the revised federal FCOI regulation, 42 CFR 50 subpart F, the PI and all Key Research personnel who contribute in a substantive way to the development or execution of a project must have an SFID on file in the ORI (Office of Research Integrity) before your application can be submitted to the NIH. Please contact Amy Melton, 304-696-4365, amy.melton@marshall.edu if you require assistance or have questions concerning the completion of the SFID form.

_____Conflict of Interest (COI) Training: In accordance with the revised FCOI regulation, 42 CFR 50 subpart F, all PIs and Key Research Personnel who contribute in a substantive way to the development or execution of a project must complete the CITI COI course upon receipt of award and before account set up/expenditure of funds.

If your project involves the following**:

_____Human Subjects: submit protocol to: Bruce Day 304-696-4303 day50@marshall.edu

_____Vertebrate Animals: submit protocol to: Monica Valentovic 304-696-7332 valentov@marshall.edu

_____Hazardous Materials: submit protocol to: Nathan Douglas 304-696-3461 douglas2@marshall.edu

_____Radioactive Materials: submit protocol to: William McCumbee 304-696-7366 mccumbee@marshall.edu

_____rDNA, Infectious Agents or Blood borne Pathogens submit protocol to: Don Primerano 304-696-7388 primeran@marshall.edu

***Protocols must be approved before awarded funds may be expended.

Upon notification of intent to apply, your Grants Officer will begin to prepare your Grants.gov package. Please send required documents to your Grants Officer as you complete them. Documents received at the last minute run the risk of being rejected by the NIH for non-compliance.

All Key Personnel, including Graduate Students****, must have an eraCommons account or the NIH will reject the application. These accounts must be set up by Lisa Daniels (adkins244@marshall.edu) prior to proposal submission. It is the account holder’s responsibility to ensure that the information in the eraCommons profile is accurate.

****NEW: As of October 2, 2014, all graduate students working on an NIH-funded research project will need to have eraCommons ID in order to fulfill the upcoming reporting requirement which must include a section to describe how individual development plans are used to identify and promote the career goals of graduate students and postdoctoral researchers associated with the award.

NOT-OD-14-113

It is also important to submit EARLY, as the NIH has eliminated the 2-day correction window (NOT-OD-11-035). For more information on post-submission materials, visit: NOT-OD-10-115

Applications cannot be changed, corrected or resubmitted once the deadline has expired. No exceptions.

SUBMIT YOUR APPLICATION EARLY!

APPLICANTS MUST FOLLOW ALL DEPARTMENTAL/COLLEGE PROCEDURES PERTAINING TO INTERNAL REVIEW.

When applicable, proof of internal review must be attached before submission.

QUESTIONS? Contact your assigned Grants Officer!