RTRN SMALL GRANTS PROGRAM

RELEASE DATE: September 19, 2014

Overview:

A strategic goal of the RCMI Translational Research Network (RTRN) is to improve minority health and to reduce ethnic and geographic disparities in health by providing modest funding for inter-institutional clinical and translational science projects across the 18 RCMI grantee institutions. To achieve this goal, a continuing initiative within RTRN is the Small Grants Program. Several important changes have been made in the reissuing of the RTRN Small Grants Program funding opportunity announcement (FOA). The key points are enumerated below.

Key Points:

1. **An Applicant may submit only one application, as a Lead or Multiple Principal Investigator.**
2. **Applicants must articulate how the proposed project falls within the scope of clinical and translational research.**
3. **Applications must represent collaborations between clinical researchers, basic science researchers and community researchers across two or more RCMI grantee institutions. All applicants must designate a primary collaborator (or Multiple Principal Investigator) from another RCMI grantee institution.**

RCMI Applicant (Corresponding or Lead Principal Investigator)	Primary Collaborator (or Multiple Principal Investigator) from another RCMI grantee institution
Clinical Researcher	Clinical Researcher
Clinical Researcher	Basic Science Researcher
Clinical Researcher	Community Researcher
Community Researcher	Community Researcher
Community Researcher	Basic Science Researcher
Community Researcher	Clinical Researcher
Basic Science Researcher	Clinical Researcher
Basic Science Researcher	Community Researcher

Additional collaborators from other National Institute on Minority Health and Health Disparities (NIMHD) programs and the inclusion of lay community members are encouraged. Applications that fail to show one of the collaborative arrangements, indicated above, will be considered nonresponsive and will not be reviewed.

4. **If the Principal Investigator is an Assistant Professor, a Mentor from another RCMI or non-RCMI school must be identified and a Mentoring Plan must be included.**
5. **For applications proposing dual- or multi-site clinical trials, evidence of matching funds and/or in-kind institutional support from each site must be provided.**
6. **The Data Coordinating Center (DCC) must be consulted to discuss data management and statistical plans in support of proposed studies. DCC services are provided in-kind and will not impact the award amount.**
7. **Applications must be submitted on-line (http://grants.rtrn.net/) and must be received no later than the application due date noted below. E-mail or paper applications will not be accepted.**

Key Dates:

LETTER OF INTENT DUE DATE: January 30, 2015 at 9:00 pm Eastern time
APPLICATION DUE DATE: February 28, 2015 at 9:00 pm Eastern time
SCIENTIFIC REVIEW PERIOD: March–April 2015
FUNDING DECISION AND APPROVAL PERIOD: May–June 2015
EARLIEST ANTICIPATED AWARD DATE: July 1, 2015

PURPOSE OF THE FOA

A long-term strategic goal of the RCMI Translational Research Network (RTRN) is to improve minority health and to reduce ethnic and geographic disparities in health. To achieve this goal, RTRN promotes synergy and coordinates the considerable multidisciplinary talents of basic, clinical and community researchers to gain new knowledge about the social, economic, behavioral, cultural, environmental, epigenetic and genetic determinants of health disparities. A continuing initiative, administered by the Research Coordinating Center (RCC) with support from the Data Coordinating Center (DCC), is the RTRN Small Grants Program, which provides modest funding for short-term, self-contained clinical and translational research projects, including feasibility studies, secondary analysis of existing data, and development of research methodology and technology, that involve collaborative partnerships across the 18 RCMI grantee institutions.

Translational Research

In the FOA for RTRN [RFA-MD-12-005: Limited Competition: Research Centers in Minority Institutions (RCMI) Translational Research Network (RTRN) (U54) (http://grants.nih.gov/grants/guide/rfa-files/RFA-MD-12-005.html)], translational research was defined as "research that aims to convert basic research advances to practical applications in humans, and research aimed at the adoption of best practices in community healthcare". In PAR-09-261: Limited Competition for Research Centers in Minority Institutions Infrastructure for Clinical and Translational Research (RCTR) [U54] (http://grants.nih.gov/grants/guide/pa-files/PAR-09-261.html), it states that translational research "includes research that ranges from the translation of basic to clinical research, to research aimed at the adoption of best practices in community healthcare." Similarly, in RFA-RM-07-007: Institutional Clinical and Translational Science Award (CTSA) (U54) (http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-007.html), it states, "translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science."

Although the terms T1 and T2 are not used in the NIH lexicon, several institutions with CTSA have developed overall and categorical definitions. For the purpose of this FOA, translational research is defined as the innovative application of basic research discoveries toward the diagnosis, management and prevention of human diseases, and the categorical definitions used by the Harvard Catalyst will be applied (Table 1).

Table 1. Translational Research Levels Used by the Harvard Catalyst (http://catalyst.harvard.edu/)

Translational Research	Definition	Examples
T1 Translation to Humans	• Findings from basic research are tested for clinical effect and/or applicability • T1 research yields knowledge about human physiology and the potential for intervention	• Preclinical and Animal Studies • Human Physiology • First in Humans (FIH) (healthy volunteers) • Proof of Concept (POC) • Phase 1 Clinical Trials
T2 Translation to Patients	• Investigations that test new interventions under controlled environments to form the basis for clinical application and evidence-based guidelines • T2 research yields knowledge about the efficacy of interventions in optimal settings	• Phase 2 Clinical Trials • Phase 3 Clinical Trials • Clinical Epidemiology
T3 Translation to Practice	• Investigations that explore ways of applying recommendations or guidelines in general practice • T3 research yields knowledge about how interventions work in real-world settings	• Phase 4 Clinical Trials • Health Services Research -Dissemination -Communication -Implementation • Clinical Outcomes Research
T4 Translation to Population Health	• Investigations that study factors and interventions that influence the health of populations • Investigations that establish new health policies • T4 research ultimately results in improved global health	• Population-level Outcome Studies • Social Determinants of Health • Behavioral Determinants of Health

Clinical Research and Clinical Trials
For the purposes of this FOA, clinical research is defined as research that involves an individual person or group of people, or that studies materials from humans, such as their behavior or samples of their tissue. Clinical trials represent a special type of clinical research that examines the safety and effectiveness of new ways to detect, treat or prevent diseases, as well as ways to improve the quality of life for patients with chronic illnesses. Typically, treatments might include new drugs or new combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments.

Community-Engaged Research
For the purposes of this FOA, community-engaged research is defined as "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people." Community-engaged research is a "vehicle for bringing about environmental and behavioral changes that will improve the health of the community and its members." It often involves partnerships and coalitions that help mobilize resources and influence systems, change relationships among partners, and serve as catalysts for changing policies, programs and practices. What characterizes community-engaged research is not the methods used, but the principles that guide the research and the relationships between researchers and the community. Thus, a central tenet to community-engaged research is a collaborative effort between community partners and researchers to engage in research that benefits community (http://grants.nih.gov/grants/guide/pa-files/PA-13-209.html).

General and Specific Examples
Applications should articulate how the proposed project falls within the scope of clinical and translational research. Moreover, the applicants must indicate the potential of the research to improve minority or rural health or minimize health gaps between health disparity populations and the general population. Projects may involve primary data collection or secondary analysis of existing datasets. Projects that examine understudied health conditions; examine the cost-effectiveness of interventions, health services, or policies for health disparity populations; dissect the social and behavioral determinants of health disparities; and/or measure the impact of the research on reducing health disparities are particularly encouraged.

General examples include, but are not limited to, collaborations across the life sciences, public health, clinical medicine, epidemiology, biostatistics, pharmacology, biomedical informatics, computational biology, ethics, social and behavioral sciences, biomedical imaging and bioengineering, law and health economics that advance our understanding about the social, economic, behavioral, cultural, environmental, and genetic and epigenetic determinants of health disparities and that improve our knowledge about biological systems to reduce the burden of disease and improve human health. Specific examples might include collaborations which include community-engaged research that:

- Test culturally relevant preventive or health-improvement interventions at the individual, family, neighborhood or community level (e.g., health literacy promotion);
- Apply innovative, culturally acceptable uses of information technology and/or social media to promote health;
- Promote innovative strategies for greater participation of health disparity populations in health research and clinical trials;
- Develop new biomarkers for the diagnosis and/or the monitoring of severity and progression of human disease;
- Develop new biomarkers for the diagnosis and/or the severity and progression of human disease.

APPLICATION

Eligibility: Any *faculty member* of the 18 RCMI grantee institutions, holding a doctoral degree and possessing the skills, knowledge and resources necessary to carry out the proposed research, is invited to submit an application. An applicant may submit only one application, as lead Principal Investigator or as one of two or more principal investigators (i.e., Multiple Principal Investigator). An applicant must have an updated Profile on the RTRN website (http://connect.rtrn.net/profilesweb/profiles.aspx), and be a member of the Translational Research Cluster System (http://www2.rtrn.net/programs/). Individuals from under-represented racial and ethnic groups, as well as individuals with disabilities, are encouraged to apply. Current and past Small Grants Program awardees may apply for continued support of their original projects or for new projects. On the other hand, individuals who currently serve as the principal investigator of active NIH R01 or P01, P20, P60, U01,

U19, U54, DP1, DP2 (or similar) and/or K99R00 grants are ineligible to apply as Principal Investigator or Multiple Principal Investigator. Similarly, those with R01-equivalent awards from the National Science Foundation, Department of Defense and national societies and foundations, such as the American Heart Association, are ineligible, as are postdoctoral fellows and graduate students.

Collaborators: All applicants must designate at least one collaborator (or Multiple Principal Investigator) from another RCMI grantee institution. Additional collaborators may be from non-RCMI grantee institutions or the lay community. The acceptable types of collaborative partnerships are shown above. **A brief but sufficiently detailed Communications Plan is required and must be included within the five-page limit of the overall application.** All RCMI collaborators must post their Profiles on the RTRN website (http://connect.rtrn.net/profilesweb/profiles.aspx) and be members of the Translational Research Cluster System (http://rtrn.net/research/research_clusters.html). The RCC Translational Cluster Liaisons and RCC Key Function Leadership Group Facilitators (http://www2.rtrn.net/programs/) are available to assist in the identification of suitable collaborators and/or mentors for prospective applicants.

Mentoring: For applicants holding the academic rank of Assistant Professor, an additional requirement is the designation of a mid-level or senior-level investigator from another RCMI grantee institution, or from a non-RCMI grantee institution, as a mentor. **A brief but sufficiently detailed Mentoring Plan is required and must be included within the five-page limit of the overall application.**

Letter of Intent: A Letter of Intent is mandatory, but is not binding. All applicants must use the Letter of Intent Template, available on the on-line grant submission system (http://grants.rtrn.net/). Apart from providing a brief project summary (50 words or less, with three key words), the Letter of Intent must indicate the type of translational research being proposed. The Letter of Intent should be submitted electronically to pbullard@hawaii.edu, with a copy to the DCC (dtcc-SGP@rtrn.net).

Submission Process: All applicants must use the RTRN Small Grants Program Template available on the on-line grant submission system (http://grants.rtrn.net/). The names of the RCMI Principal Investigator or Program Director and the Responsible Institutional Official of the applicant institution must be provided on the face page. The full research proposal is limited to five (5) pages: the Specific Aims page is limited to one (1) page and the Research Strategy component may not exceed four (4) pages (typed single-spaced using 11-pt Arial on one side of the page). All tables, graphs, figures, diagrams, charts and other displays must be included within the five-page limit. Also, the five-page application must include a Communications Plan (including the designated collaborator) and/or a Mentoring Plan (if applicable, including the designated mentor), and **a timetable for seeking subsequent extramural support.** Cited references are limited to one (1) page.

The following items are not counted in the five-page limit: Biosketches and Other Support information of the principal investigator(s), collaborator(s) and mentor; full descriptions of Protection of Human Subjects from Research Risk; Inclusion of Women, Minorities and Children in Research; Care and Use of Vertebrate Animals in Research; and Biohazards and Select Agents; a Targeted/Planned Enrollment Table Format Page. Evidence of IRB applications or approvals is required at the time of submission.

Letters of Support: Applicants must include letters of support from their collaborator(s), and if applicable, from their mentor(s). Applicants must also provide a letter from the RCMI Principal Investigator or Program Director, indicating specific information about administrative and/or institutional support. Applications proposing dual- or multi-site clinical trials must be provide letters of support, indicating matching funds and/or in-kind institutional support from each site, from the RCMI and/or RCTR Principal Investigator or other institutional official.

All applicants are required to use services from the RTRN DCC: (1) Applicants should review the services offered and participate in a scheduled teleconference with the DCC to discuss the use of these services; (2) Using your final proposal title, submit a Cost Proposal Request Form (CPR Form) located on the RTRN website (http://www2.rtrn.net/researchhub/?page_id=1264); and (3) Obtain and submit a Cost Estimate and Letter of Support from the DCC with your application. Although mandatory, DCC services will be provided at no cost to applicants. That is, DCC services for Small Grants Program applications will be provided in kind.

Budget and Mechanism of Support: A non-modular itemized budget, with justification, is required, using the designated pages in the RTRN Small Grants Program Template. Funds may be requested for costs associated with personnel salaries, small equipment (not to exceed $5,000), supplies and travel. For successful

applicants, subcontracts will be made from the Morehouse School of Medicine to the awardee institutions. The applicant (and collaborator) will be solely responsible for planning, directing, and executing the research.

Funds Available: A $250,000 commitment will fund five or more inter-institutional collaborative projects. Applicants may request an annual budget with direct costs of up to $50,000. **No provisions for indirect costs will be allowed.** Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size of each award may also vary. All projects must be completed within the project period, with an end date of June 30, 2016. No provisions will be allowed for carryover requests.

SCIENTIFIC REVIEW

RCMI Program Directors/Principal Investigators and other RCMI faculty with subject-matter expertise and NIH study section experience, as well as members of the RTRN External Advisory Committee (EAC) and RCMI/RCTR EAC will serve as reviewers. In all cases, individuals with conflicts of interest will not be assigned as reviewers. NIH-type review criteria and 9-point scoring scale will be used, based on strengths and weaknesses. Briefly, the initial merit review of applications for support through the Small Grants Program will be based on the following six criteria: collaborations and partnerships; significance; innovation; approach; investigators; and environment. In addition, the use of DCC services [e.g., biostatistics, clinical data management, communication support, research networking (Profiles), resource discovery (eagle-i) and technology services] and the overall likelihood that support will be leveraged into a competitive NIH grant application will be assessed.

Collaborations and Partnerships: Does the application demonstrate a collaborative arrangement between clinical researchers, community researchers and/or basic science researchers from two or more RCMI grantee institutions? Does the collaborative arrangement conform to one of the types of partnerships summarized in the FOA? Do the applicant and collaborators have the appropriate academic qualifications and research experience and skills to successfully conduct the proposed research? Has the applicant described how she or he will use the Data Coordinating Center (DCC) to facilitate project implementation? If applicable, are plans included to address ethical issues and/or regulatory concerns?

Significance: Does this study address an important health problem? Does the proposed research fall within the scope of clinical and translational research? What translational research level best characterizes the proposed research? If the aims of the study are achieved, how will health outcomes be improved or health disparities be reduced? What effects will the study have on the concepts, methods, technologies, treatments, services and/or preventive interventions that drive the field?

Innovation: Is the project original and innovative? Does the proposed research challenge existing paradigms or clinical practice or address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies?

Approach: Are the conceptual or clinical framework, design, methods and analyses adequately developed, well integrated, well reasoned and appropriate to the aims of the proposed research? Does the applicant acknowledge potential problems and consider alternative strategies? Can the aims be accomplished in one year? Is the research plan too ambitious? Is a timetable provided for plans to seek subsequent or supplemental extramural support? If the project involves clinical research, are the plans for the protection of human subjects from research risks, and the inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the proposed scientific goals? Is the Communications Plan sufficiently detailed to ensure that the collaborative team is sufficiently agile to respond rapidly to unexpected problems or pitfalls?

Investigators: Are the applicant and collaborator(s) appropriately trained and well suited to conduct the proposed research? Is the proposed research appropriate to the experience level of the applicant and collaborator(s)? Does the investigative team bring complementary skills or experience to the project? Does the applicant show evidence of scientific productivity and scientific achievement, as measured by the number and quality of publications and extramural funding record? If the applicant is an Assistant Professor, has she or he designated a senior investigator from another RCMI school as a mentor? Are the Mentoring Plan and Communications Plan sufficiently detailed to ensure beneficial outcomes?

Environment: Does the scientific environment in which the study will be performed contribute to the probability of success? Does the proposed research benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support, such as faculty-release time, and/or matching funds?

FUNDING PRIORITIES AND DECISIONS

During the past five funding cycles of the RTRN Small Grants Program, 44 awards have been made. The vast majority of awards were made to projects involving basic science questions, without involvement of human subjects or patient tissues or communities. While RTRN recognizes the critical importance of basic science research and of preclinical studies using animal models of human diseases, the current FOA focuses on fostering clinical and translational research involving community engagement and research beyond the so-called T1 level (except for dual-site Phase 1 Clinical Trials and First-in-Humans studies). Specifically, funding priorities will be given to T2, T3 and T4 research and to inter-institutional research projects involving community engagement. The types of collaborative partnerships, shown above, are meant to guide the research questions and study designs.

Applications that demonstrate a cross-disciplinary approach to reducing health disparities and show convergence of expertise between the applicant and collaborator(s) will be considered highly responsive to this FOA. Funding decisions will be based on priority scores, with direct oversight from the Protocol Review Subcommittee and ratification by the RTRN Steering Committee, and final approval by NIMHD. Awards will be given preferentially to applications that arise from active participation in one or more of the 10 existing Translational Research Clusters. Also, to more broadly promote translational science, awards will be distributed across RTRN Clusters, provided the proposed research is meritorious. The expectation is that data generated from the Small Grants Program will be successfully leveraged into multi-institutional collaborative NIH grant applications.

Post-Award Requirements. Each Small Grants Program awardee will be required to submit a written summary of research productivity and progress, which will be included in the RTRN Annual Progress Report. Progress reports must be submitted at six and 12 months of the project period. Grant Submission and Publication updates will be requested twice yearly thereafter. Publications arising from support through the RTRN Small Grants Program must conform to the NIH Public Access Policy. This Policy, which ensures that the public has access to the published results of NIH-funded research, requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central *upon acceptance for publication*. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication (http://publicaccess.nih.gov).

INQUIRIES

We encourage inquiries concerning this FOA. Details will be sent to the comprehensive RTRN listserv and made available on the RTRN website at http://www2.rtrn.net/rtrn-small-grants-program/. In addition, informational webinars for prospective applicants will be held on several occasions to answer any questions.

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