University of Massachusetts Center for Clinical and Translational Science

July 2015

Volume 1, Issue 6

Important Information to the Medical School Community about the Upcoming AAHRPP Accreditation Site Visit

The University of Massachusetts Medical School is seeking accreditation of its Human Research Protection Program (HRPP) from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). Accreditation signals our commitment to protection of our research subjects and the highest quality in human subject research, and is increasingly a requirement to participate in multi-center clinical studies. As a part of the accreditation process, AAHRPP will be sending site visitors to UMMS to conduct an evaluation.

We have recently been notified that the accreditation site visit for UMMS is scheduled to occur September 1-3, 2015. The purpose of this notice is to inform you about the site visit as well as training sessions open to all members of the community involved in human subjects research.

What Is the Human Research Protection Program?

The UMMS HRPP describes a comprehensive system put into place to support the protection of the rights and welfare of subjects in Human Research at our institution. Components of this system include institutional components (including but not limited to the IRB, Research Integrity and Conflict of Interest programs, the Office of Clinical Research, UMMS senior leadership, Radiation Safety and Biosafety committees) *as well as every investigator and study team member involved in human research*. For more information about the HRPP at UMMS, please visit: http://www.umassmed.edu/ccts/human-research/

Who Will Be Involved In And Impacted By the AAHRPP Site Visit?

The AAHRPP site visitors will interview individuals involved with managing or supporting components of the HRPP, as well as select Principal Investigators and study team members involved in human research. AAHRPP is expected to provide the list of Principal Investigators and study team members to UMMS on or around July 15, 2015, and selected individuals will be notified by the UMCCTS. It is critical that, if selected, you are available for a brief interview with the site visitors. We understand that the site visit dates are within a very busy time of year, and we will work to avoid disruption to schedules to the best of our ability.

What Can The UMMS Community Expect From the AAHRPP Site Visit?

Individuals and groups selected for interview by AAHRPP will be notified by UMCCTS Office of Clinical Research and scheduled for confidential interviews with the site visitors. If you are an Investigator or study team member and are contacted by UMCCTS as a selected informant, you will be expected to be familiar with applicable Human Research Protection Program requirements and be aware of where to find support information and resources.

How Is UMMS Preparing For the AAHRPP Site Visit?

The UMCCTS is conducting primary site visit preparation through two events:

Consultants from WIRB Copernicus Group (WCG) will be onsite August 24-25 to conduct preparation sessions with individuals selected for interview by Site Visitors. These sessions will cover 1) what to expect and 2) how best to respond to site visit inquiries.

UMCCTS will be conducting HRPP "Bootcamp" sessions to review key HRPP topics. While those selected for site visit participation are strongly encouraged to attend, these sessions are open to everyone in the human research community.

The dates of the Bootcamp sessions are:

Date	Topic
Thursday, July 16, 2015	Human Research, Resources and Feasibility
Thursday, July 30, 2015	Conflict of Interest in Human Research
Tuesday, August 11, 2015	Informed Consent
Tuesday, August 25, 2015	PI Responsibilities, Oversight and RNI

All sessions will be held from 8:00 – 9:00 am

Conference Room S2-310, University Campus, Worcester

Questions about these sessions can be directed to HRPeducation@umassmed.edu.

In addition to these sessions, members of the clinical research community are encouraged to review key information on the UMCCTS HRPP website at
http://www.umassmed.edu/ccts/human-research/

http://www.umassmed.edu/ccts/news/2015/July/aahrpp-accreditation-site-visit/

If you have questions about the UMMS AAHRPP accreditation process, please contact Meg Johnson at Meg.Johnson@umassmed.edu or at (508) 856-5152.

To learn more about AAHRPP, AAHRPP accreditation or to view a list of accredited institutions, visit: http://www.aahrpp.org/

M2D2 Open House & Networking Event

Wednesday, July 15, 2015
6:00 – 8:00 pm
110 Canal Street, 4th Floor
Lowell, MA 01852

The Massachusetts Medical Device and Development Center (M2D2) has expanded and is having an open house and networking event to show off our new light and bright, fully equipped shared lab facility, at **110 Canal Street in Lowell, MA**. We are ready to welcome many more medical device and biotech start-up entrepreneurs!

The 11,000 square foot center is made up of a fully-equipped, shared lab facility that can house 50 researchers and also includes plenty of co-working and meeting spaces. Add in parking and its close (3-block, 7 minute walk) proximity to the MBTA commuter rail, and you have the perfect new home for Boston start-ups!

Start-up companies and entrepreneurs utilizing M2D2's new center will have access to all that the UMass Lowell and the UMass Medical School in Worcester have to offer. Engineering, prototyping, clinical review, animal trials, clinical trials, business mentoring, and partnerships with investors are all available at their fingertips.

Please come help us celebrate this exciting time with networking opportunities, pizza & light refreshments (including beer and wine), as well as poster previews of Medical Devices, biotech and technology of several Medical Device start-up companies that have and are being helped by M2D2.

REGISTER NOW!

UMass Investigators receive FREE ADMISSION!

Contact Ruth_Dubey2@uml.edu or 978-934-3499 to take advantage of this great opportunity.

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dis·sem·i·nate
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How to Share Your Science

Telling Tales

By: Sally A. Gore, MS, MSLIS, Research Evaluation Analyst, UMCCTS

Everyone loves a good story. Perhaps this is why storytelling has become a focus of research dissemination of late. One of the real barriers to reducing the time between the discovery of an effective drug and/or other intervention and its implementation into clinical practice is the lack of effective dissemination. Success stories are one way to spread the word about research findings, to reach a wider audience, and ultimately to overcome this obstacle.

There are a number of good resources available to help you think about your story and how to put it together. Thanks to the Outreach Evaluation Resource Center of the National Network of Libraries of Medicine (http://nnlm.gov/evaluation), I recently discovered several available through the Centers for Disease Control:

- *Tips for Writing an Effective Success Story*, CDC Division of Oral Health (http://www.cdc.gov/oralhealth/state_programs/success-story-tips.htm)
- *Impact and Value: Telling Your Program's Story*, CDC Division of Oral Health (http://www.cdc.gov/oralhealth/publications/library/pdf/success_story_workbook.pdf)
- *How to Develop a Success Story*, CDC Division of Adolescent & School Health (http://www.cdc.gov/healthyyouth/stories/pdf/howto_create_success_story.pdf)
- *Success Story Data Collection Tool*, CDC Division of Oral Health (http://www.cdc.gov/oralhealth/publications/library/pdf/ss_data_collection_tool.pdf)

The National Center for Advancing Translational Science (NCATS) encourages clinical researchers to tell the stories of their work (http://ncats.nih.gov/pubs). As such, the UMCCTS is beginning to actively seek out, collect, and write the stories of our researchers and the discoveries they're making. **YOU CAN HELP!** Tell us your story and we'll share it with the appropriate audiences and stakeholders. Send your stories or ideas to Sally Gore, sally.gore@umassmed.edu, and we'll help you tell your tale.

UMCCTS Pilot Project Awards Update

By: Sally A. Gore, MS, MSLIS, Research Evaluation Analyst, UMCCTS

Since first granting Pilot Project Awards in 2007, the UMass Center for Clinical and Translational Science has provided more than $5 million dollars to 37 lead investigators.
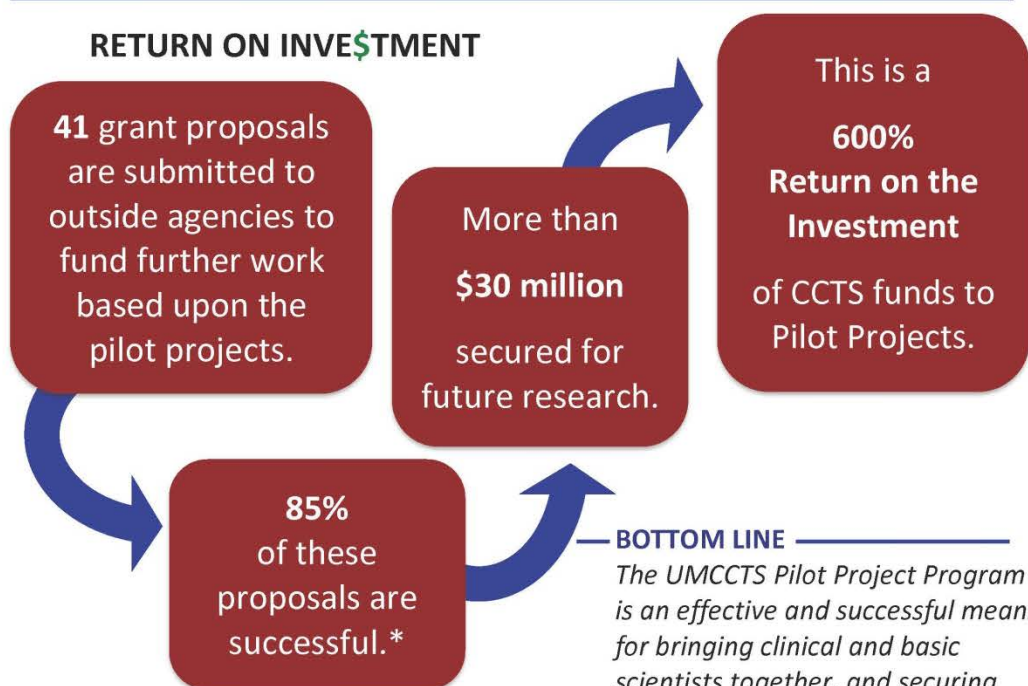
What have these researchers done with this investment?

TEAM SCIENCE

All project teams display a mix of researchers and trainees.

- Investigators
- Trainees
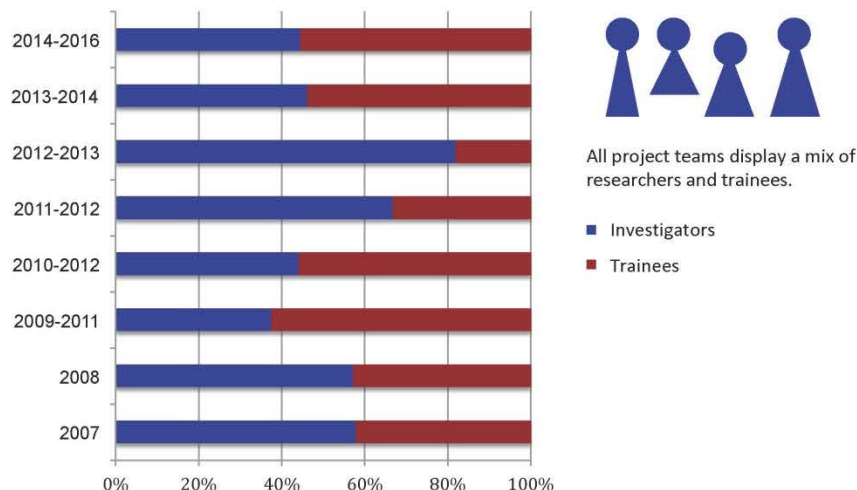
The projects have involved 84 collaborating investigators, 70 trainees, and a multitude of students from all of the Schools within UMMS, as well as some from area high schools and colleges. All teams display a mix of experienced investigators working with early researchers and/or trainees.

RETURN ON INVE$TMENT

41 grant proposals are submitted to outside agencies to fund further work based upon the pilot projects.

85% of these proposals are successful.*

More than **$30 million** secured for future research.

This is a **600% Return on the Investment** of CCTS funds to Pilot Projects.

*Some grant applications are still pending review.

— BOTTOM LINE —————

The UMCCTS Pilot Project Program is an effective and successful means for bringing clinical and basic scientists together, and securing funding for future research.

From the June 29, 2015 UMass Memorial Health Care News&Views

Health care systems like UMass Memorial Health Care are switching to the medical coding system ICD-10 on October 1, 2015. What is ICD-10? It stands for "International Classification of Diseases" and this is the 10th version (currently, we are using ICD-9 codes). We use these codes to keep track of a patient's diagnosis and any inpatient procedures.

What are we doing to get ready for ICD-10?

UMass Memorial identified all job functions that use the ICD codes to determine the training needed. Currently, physicians/mid-levels and coders are training; other clinical and administrative staff will receive education/training beginning in late July.

Questions? Email ICD-10FAQ@umassmemorial.org.

Watch Video: ICD-10 Important Changes for Our Organization, Nation

This video provides important information about converting to ICD-10 medical coding at UMass Memorial Health Care

https://www.youtube.com/watch?v=hrk1IPIk3kk&feature=youtu.be

Common Questions on Clinical Trial Agreements

UMCCTS Office of Clinical Research (OCR) Staff provide helpful tips and information to investigators, study teams and departments

Tips for: Investigator Initiated Studies: Where to begin?

By: Kathy Beauregard, Sr. Contract Administrator

Your investigator went to a meeting and pitched his/her idea to a Biomedical company (drug or device) and has been asked to submit a proposal and budget for their review. Since this is not a "grant" and it is not a standard industry clinical trial, where do you begin?

First: Before you pitch and during negotiations, consider how to protect UMMS intellectual property. Consult with UMMS Office of Technology Management for assistance.

Second: As soon as you determine that the study involves human subjects in any way, contact the UMCCTS Office of Clinical Research as soon as possible. We will negotiate and execute the funding agreement and can help identify what costs should be captured and budgeted so all potential costs can be identified and covered by sponsor or other funding source.

Third: As the developer and "owner" of the protocol, it is likely that you assume the regulatory obligations of the "Sponsor-Investigator" if the project is FDA-regulated. The UMCCTS Human Research Protection Program (HRPP) Quality Improvement & Education division of OCR can help educate investigators and additional guidance resources are available through the IRB and HRPP websites.

Contact the Office of Clinical Research for assistance, clinicalresearch@umassmed.edu

Check out the website, http://www.umassmed.edu/ccts/human-research/Clinical-Research-Agreements-and-Budgets/

UMMS Human Research Protection Education Program

Clinical Research Professionals Group

The Clinical Research Professionals Group (CRPG) consists of clinical research staff throughout the University of Massachusetts Medical School (UMMS), including Principal Investigators, Study Coordinators, Research Nurses, Administrators, and others. All research staff are invited to be part of the CRPG regardless of their role or background in clinical research.

CRPG meets once per month. Meetings are a forum for presentations and discussion on a variety of topics, including:

- enhancing the protection of human subjects in research

- best practices in clinical research

- policies and procedures related to the implementation of human subjects research

If you are interested in being part of the CRPG to receive important announcements, please email HRPeducation@umassmed.edu to be added to the email distribution list.

Date	Time	Location at UMMS
Wednesday, July 15	12:00 – 1:00 pm	Hiatt Auditorium S1-608
Tuesday, August 11	2:30 – 3:30 pm	Hiatt Auditorium S1-608
Friday, September 11	9:00 – 10:00 am	Hiatt Auditorium S1-608
Monday, October 19	12:00 – 1:00 pm	Hiatt Auditorium S1-608

For questions about educational offerings or if you have a topic you would like to see the HRPP Education Program address, please email HRPeducation@umassmed.edu

UMMS Human Research Protection Education Program

AAHRPP "Boot Camp"

Site Visit Preparation

Investigators and study staff are encouraged to attend this series intended to prepare potential *key informants* for AAHRPP interviews.

8:00-9:00 am

S2-301 Conference Room, UMMS Worcester campus

Date	Topics
Thursday, July 16	Human Research, Resources & Feasibility
Thursday, July 30	Conflict of Interest
Tuesday, August 11	Informed Consent
Tuesday, August 25	PI Responsibilities, Oversight & RNI

Register or questions – email: HRPeducation@umassmed.edu

Program in Bioinformatics and Integrative Biology

Guest Speaker:

Aashish Jha, PhD

Institute for Genomics and Systems Biology
Department of Human Genetics
The University of Chicago

"Understanding the genetic basis of complex traits in fly and human"
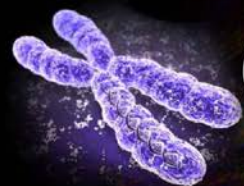
Friday
July 17, 2015
11:00 AM
AS6-2072

Host: Elinor Karlsson, Assistant Professor
Bioinformatics and Integrative Biology
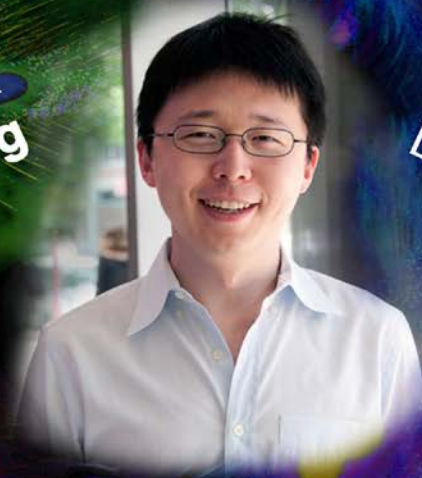*Presented By*
University of Massachusetts Medical School

UMMS Human Research Protection Education Program

Looking to get your study approved *quickly*?
Want to make your sponsor *happy*?

Come learn how the
UMMS IRB and Western IRB can help!

Who? All UMMS principal investigators, study coordinators, study nurses, and research administrators are **strongly** encouraged to attend.

What? UMMS will explain *when and how* to use WIRB. WIRB will explain *how* to use their portal system, **Connexus**.

Time will be reserved for **Q&A**.

When? **Thursday, July 23, 2015**

10:00 am – 12:00 pm *OR* 2:00 pm – 4:00 pm

Where? Hiatt Auditorium, S1-608, University Campus, Worcester

Why? To speed the review process with UMMS IRB and WIRB to get your study up and running faster.

RSVP appreciated to HRPeducation@umassmed.edu by Friday, July 10, 2015

UMMS Human Research Protection Education Program

Information Security & Privacy for Researchers

Brian Coleman, CISSP, CISM
Information Security Officer

Who? All UMMS principal investigators, study coordinators, study nurses, and research administrators are **strongly** encouraged to attend.

What? This presentation will address *pitfalls* and *best practices* for data security in human research.

Time will be reserved for Q&A.

When? **Friday, July 24, 2015**

11:00 am – 12:00 noon

Where? **Lazare Auditorium S1-607**, University Campus, Worcester

RSVP appreciated to HRPeducation@umassmed.edu by Wed. July 22.

UMMS Human Research Protection Program (HRPP)

Quality Assurance/Quality Improvement and Education

invite you to attend the…

Basic Clinical Research Coordinator Course

Thursday, August 13, 2015

9:00 am – 1:00 pm

University Campus, Ambulatory Care Center, 7th Floor

Hancock Hill Conference Room(07-050)

This introductory course is geared toward new coordinators and will introduce basic concepts related to coordination of human subject's research. Basic Good Clinical Practice (GCP) concepts will be introduced, but this is not a GCP course. An intermediate course and sessions on advanced HRP topics are in development.

Please register by emailing: HRPeducation@umassmed.edu

Space is limited so enrollment will be on a first come, first serve basis.

Beverages and light refreshments will be provided.

A Survey of Clinical Opinion on the Utility of Point-of-Care Testing (POCT) Devices

As part of an inter-institutional MOU, the UMass Center for Clinical and Translational Science (UMCCTS) is facilitating a research project with the University of Ulster, Nanotechnology & Integrated Bioengineering Centre, School of Engineering, Northern Ireland regarding the clinical utility of point-of-care testing (POCT) devices. A PhD student, Alistair Quinn, visited UMass in June and conducted over 20 interviews.

What is the purpose of the study?

There are indications from published literature that despite rapid advances in the development of new diagnostic markers that underpin the clinical utility of POCT, the uptake and utilization of these technologies is less than might be expected. The nature and relative importance of the issues that have been identified as possible impediments to the more widespread adoption of POCT are not fully understood. To better explain these underlying issues, it is deemed important to gain relevant information as to the utility of POCT devices within the clinical environment. As POCT is used internationally, it is important to compare experiences in a range of countries operating within different healthcare provision regimens.

A complete description of the study is available on the UMCCTS website at,
http://www.umassmed.edu/ccts/news/2015/June/point-of-care-testing

If you are interested in participating in this study, please contact Nate Hafer, PhD,
nathaniel.hafer@umassmed.edu

The NIH Lasker Clinical Research Scholars Program

A Unique Bridge for Early Stage Clinical Investigators

The National Institutes of Health, in partnership with the Lasker Foundation, is pleased to announce the **2015 Lasker Clinical Research Scholars Program**. This is an opportunity for 10 to 12 years of funding for clinical researchers.

This unique program provides Scholars with 5 to 7 years of support as an independent principal investigator in the NIH Intramural Research Program, followed by three years of continued financial support, either at the NIH or at an outside medical center/research institution.

Qualifications/eligibility:

Candidates must have a clinical doctoral degree (MD, MD/PhD, DO, DDS, DMD, RN/PhD or equivalent) and a professional license to practice in the United States. The program is intended for investigators at the early stages of their independent careers, and at the time of application, candidates must be no more than 10 years from completion of their core residency training. Candidates generally will have completed or will be completing a post-residency clinical fellowship and will have demonstrated significant patient-oriented research experience to qualify for a tenure-track level appointment.

To apply: Learn more at http://www.nih.gov/science/laskerscholar/

> **Application deadline is August 27, 2015**

Questions can be directed to Dr. Charles Dearolf, Assistant Director for Intramural Research, at LaskerScholar@nih.gov

The National Center for Advancing Translational Sciences

Collaborative Innovation Award

The National Center for Advancing Translational Sciences (NCATS), National Institutes of Health has announced a **Collaborative Innovation Award, Clinical and Translational Science Award (CTSA) Program U01 and pre-application X02**.

These FOAs aims to support applications for innovative collaborative investigations (**involving three or more CTSA sites**) into improvements of the methods of translational research, at any step in the translational spectrum (T1-T4). It is anticipated that the combined effort of three or more CTSA hubs in flexible networks will substantially enhance the effectiveness of the CTSA consortium to address high priority translational research questions. These FOAs therefore aim to support innovative and collaborative experimental translational research projects carried out in the CTSA consortium that have the following characteristics:

- Such projects should develop a new technology, method, or approach that addresses a general roadblock in science and/or operations that limits the efficiency and effectiveness of translation.
- Such projects should demonstrate in one or more use cases whether the tool, method, or approach is effective in accelerating translation, utilizing clear and meaningful metrics and outcomes, when implemented across multiple CTSA hubs.
- Such projects should advance collaboration, building on existing strengths and resources of individual CTSA hubs.
- What constitutes success of the proposed project can be defined and measured.

Please see complete details in the 2 links below: There is a pre-application step (X02) followed by an invited full application (U01).

X02 URL: http://grants.nih.gov/grants/guide/pa-files/PAR-15-173.html

U01 URL: http://grants.nih.gov/grants/guide/pa-files/PAR-15-172.html

If you are interested in submitting a pre-application, please contact Nate Hafer at least 2 weeks before the grant deadline at nathaniel.hafer@umassmed.edu or 508-856-2511

The National Center for Advancing Translational Sciences and National Library of Medicine

Clinical and Translational Science Award (CTSA) Network Recruitment Innovation Centers (RICs) (U24)

The National Center for Advancing Translational Sciences (NCATS) and National Library of Medicine, National Institutes of Health has just announced a new **Clinical and Translational Science Award (CTSA) Network Recruitment Innovation Centers (RICs) (U24).**

Translating laboratory and clinical discoveries into interventions that improve human health is a complex process that typically takes years of effort. Multi-site clinical trials are a critical step in the translation pathway that allows preventive, diagnostic, or therapeutic interventions to benefit individual and public health. These trials may require substantial sample sizes to credibly test hypotheses. However, such trials often experience delays or even fail entirely due to challenges in recruiting participants. Such challenges are a multi-faceted problem with scientific, psychological, sociological, economic, political, and ethical dimensions. Addressing these challenges therefore requires a multi-faceted and "out of the box" approach, rather than small changes only to the status quo. Participant recruitment may benefit from innovation in the following areas:

- Access to data on the availability of potential participants rather than reliance on clinician estimates.
- Data that provide sufficient detail to take into account the specific entry criteria of a given protocol.
- Recruitment strategies that employ innovative approaches from other fields such as communications.
- Sharing of recruitment strategies, materials, and associated outcomes among participating research sites or between projects for ongoing innovation and improvement so that best practices can be developed and disseminated.
- Engagement of relevant stakeholders (e.g. potential participants and referring clinicians) early in the recruitment process.
- Reducing burden on participants, and making referrals easy for busy clinicians who may have many priorities competing for their time.
- Reframing proposed solutions to recruitment challenges as testable scientific hypotheses to allow for data-driven process selection.

This FOA is intended to develop and implement innovative informatics-driven approaches as well as the ethics and policy frameworks that will accelerate the design, conduct, and completion of multi-site clinical trials by establishing Clinical and Translational Science Award (CTSA) Recruitment Innovation Centers (RICs).

Complete details: http://grants.nih.gov/grants/guide/rfa-files/RFA-TR-15-004.html

If you are interested in submitting an application, please contact Nate Hafer as soon as possible at nathaniel.hafer@umassmed.edu or 508-856-2511

The National Center for Advancing Translational Sciences and National Institute on Aging

CTSA Network – Trial Innovation Centers (TICs) (U24)

The National Center for Advancing Translational Sciences (NCATS) and National Institute on Aging, National Institutes of Health has just announced a new **Clinical and Translational Science Award (CTSA) Network – Trial Innovation Centers (TICs) (U24).**

The purpose of this funding opportunity announcement is to invite applications to establish Trial Innovation Centers (TICs) for the Clinical and Translational Science Award (CTSA) program. The TICs will be lead centers of an innovative expert network that will accelerate the implementation of multi-site studies by the CTSA Network. National Institutes of Health (NIH) supported studies are the focus of this initiative; however, the capacity created might also be of interest and useful for trials conducted by other federal agencies, as well as by the private and non-profit sectors.

The TICs will transform the CTSA network's ability to implement multi-site studies by adding innovative network capacity to the existing strength at the CTSA Hubs. The TICs will not be specific to one disease, but have the capacity to identify and coordinate a cadre of specialist investigators from across the CTSA network to implement studies efficiently in response to a broad range of disease specific opportunities. Select TICs, however, will have particular expertise to conduct multi-site studies with special populations, such as pediatric or geriatric subjects.

Please see complete details in the link below:

http://grants.nih.gov/grants/guide/rfa-files/RFA-TR-15-002.html

If you are interested in submitting an application, please contact Nate Hafer as soon as possible at nathaniel.hafer@umassmed.edu or 508-856-2511

Smith Family Awards Program for Excellence in Biomedical Research

A PROGRAM OF THE RICHARD AND SUSAN SMITH FAMILY FOUNDATION

Overview

In 1991, the Smith Family Foundation created a grants program to support promising junior faculty who were beginning to establish their own independent laboratories and research programs. Now in its 24th year, this Program has funded 143 scientists for a total of $26.9 million.

Application for the Smith Family Awards Program for Excellence in Biomedical Research may focus on all fields of basic biomedical science. Investigators in the physical sciences (physics, chemistry and engineering) with biomedical research projects are also encouraged to apply.

Online Application Deadline: Thursday, September 3, 2015 at 12:00 noon EST

Funding Period: December 1, 2015 – November 30, 2018

Award Amount: Up to $300,000 three-year awards, inclusive of 5% institutional overhead.

For complete information: www.tmfgrants.org/Smith

The Medical Foundation
A division of Health Resources in Action

The Smith Family Awards Program for Excellence in Biomedical Research is managed by The Medical Foundation division.

UMass Center for Clinical and Translational Science

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Worcester, MA 01605-0002

Website: http://www.umassmed.edu/CCTS

Email: ccts@umassmed.edu

Contact us: http://www.umassmed.edu/ccts/contact-us/

Sign-up for Membership: http://www.umassmed.edu/ccts/ccts-sign-up-for-membership/

Please remember to cite the CTSA Grant # UL1TR000161 in all supported journal publications.
http://www.umassmed.edu/ccts/nih-citation-requirements/