NEWS

HHS Takes Steps to Provide More Information About Clinical Trials to the Public

On September 16, 2016, in an effort to make information about clinical trials widely available to the public, the U.S. Department of Health and Human Services (HHS) issued a final rule specifying requirements for registering and reporting summary results information to ClinicalTrials.gov. The new rule expands the legal requirements for submitting registration and results information for certain clinical trials involving U.S. Food and Drug Administration (FDA)-regulated drug, biological and device products to ClinicalTrials.gov. At the same time, the National Institutes of Health issued a complementary policy for registering and submitting summary results information to ClinicalTrials.gov for all NIH-funded clinical trials, including those not subject to the final rule. These actions are important steps to honor our commitments to clinical trial participants to share the knowledge gained from their participation in order to achieve the greatest benefit to human health.

Since many of you are likely to be affected by these changes, we encourage you to read the NIH news release along with related materials to learn more about these important developments and to contact your Office of Research for any questions pertaining to this announcement.

DID YOU KNOW?

Pathway to Independence (PI) Working Group

The UMass Center for Clinical and Translational Science and the UMMS Office of Research "R-Club" was established in October 2014. Drs. Beth McCormick and Robert Goldberg are pleased to announce the third annual offering of the Pathway to Independence (PI) Club at UMMS, an auxiliary of the "R-Club".

The Pathway to Independence (PI) Club at UMMS is a working group that is available for all current and past K awardees and junior faculty who are contemplating the submission of an R-type grant (e.g., R01, R03, R21) to the NIH during the coming academic year as well as for those who might be considering foundation or other types of awards. This working group is particularly geared to young investigators who will be submitting grant proposals as part of their career pathway and are committed to a research career. This working group is intended to enhance, and not replace, mentoring by peers and senior faculty.

Don’t miss out on this excellent learning opportunity! Learn More
Award & Writing Group "K-Club", established in 2007, is co-lead by Drs. Douglas Ziedonis and Sherry Pagoto. Most faculty who participate and apply for a research career award have been very successful in getting funded (>80% success). The group meets monthly to provide information and feedback on academic career development and on preparing a Research Career Award application.

Faculty will receive:

- Feedback on CV development
- Help on preparing NIH biosketches
- Support on creating yearly career development plans
- Individualized help on developing career goals and program of research
- Support with writing the career development grant application
- Guidance on selecting and working with primary and secondary mentors (if needed)

Don’t miss out on this great educational opportunity! Learn More

EVENTS

October 2016 Events

Human Research Protection Program (HRPP)
Upcoming Educational Opportunities

Clinical Research Professionals Group (CRPG) Meetings:

Monday, October 17, 2016
2:00 pm - 3:00 pm
Hiatt Auditorium S1-608, UMMS, Worcester

Thursday, November 17, 2016
2:00 pm - 3:00 pm
Hiatt Auditorium S1-608, UMMS, Worcester

Learn More

~New~ HIPAA and Research Series

Mark your calendars! Join us Wednesdays in November for a series on HIPAA and research with joint presentations from the Privacy Officers, IRB, and IT.

Sign-up for one session or all sessions.

Wednesdays, Amphitheater I, S2-102, UMMS, Worcester

November 2, 2016
4:00 - 5:00 pm
"Basics of HIPAA and Research"

November 9, 2016
8:00 - 9:00 am
"Research, Privacy and the EHR"

November 16, 2016
8:00 - 9:00 am

November 30, 2016
12:00 - 1:00 pm
Watch the New Release in NRMN's Health Research Talks Video Series

"What is Community-Based Participatory Research (CBPR) and Why Do It?" featuring Monica L. Baskin, PhD

In this fourth installment, Dr. Monica Baskin of the UAB Division of Preventive Medicine introduces Community-Based Participatory Research (CBPR), its guiding principles, CBPR tools in application, and the foremost challenges and opportunities for those engaging in it.

Watch now!

I-Corps Program at the UMCCTS

Register for the second informational session!

Are you interested in the business of science? Want help translating your research into better health?

The new I-Corps Program at the UMCCTS, a joint MassTERi/UMass Center for Clinical and Translational Science initiative, is designed to support the translation of biomedical research by providing early-stage education and strategic guidance to faculty, staff and students during the ideation phase of technology development.

This four-week course will be held in the Spring 2017. Designed specifically for the biomedical researcher at UMass, it guides interdisciplinary teams through a hands-on process of understanding the market for their technology utilizing a proven customer discovery methodology.

Please join us for a no-obligation, information session on:

Monday, October 17, 2016
12:00 - 1:00 pm
Albert Sherman Center, AS7-2072
UMass Medical School

Register today!
John Van Drie, PhD, Owner and President, Van Drie Research, LLC
Pharma experience includes, BioCAD, Pharmacia, Pfizer, Vertex, Novartis

UMass Center for Clinical and Translational Science Newsletter, Vol. 2016 [2016], Iss. 10, Art. 1
Department of Microbiology and Physiological Systems

Presents the

Seventeenth Fred Fay Lecture

“Nanoscoppy with Focused Light”

Stefan W. Hell, Ph.D.
Professor and Director
NanoBiophotonics Department
Max Planck Institute for Biophysical Chemistry
Göttingen, Germany

http://www.mpp.mpg.de/150445549/research

Tuesday, October 18, 2016
3:00 p.m.
Albert Sherman Center Auditorium
Rm. AS2.2102, 2nd Floor

Host: Ann R. Rittenhouse, Ph.D.
508-856-3735

A reception will follow the lecture in the Cube Suite
Room AS3.2119

SELECTED PUBLICATIONS


This MassTERi event is sponsored by the UMass Office of Innovation and Business Development and the UMass Center for Clinical and Translational Science.
Pharmaceutical Innovation: Why Do Innovative Drugs "Die" Along the Way?

Thursday, October 20, 2016
Multi-Purpose Room EAST, 1st floor
Albert Sherman Center
University of Massachusetts Medical School

Register today!

4:00-5:00 pm - Lecture and Case Study
5:00-5:30 pm - Networking (refreshments served)

Lecture and Case Study: Some of the principles of innovation will be discussed including the opposable mind, the role of midnight projects and failure as a metric. The reasons why innovative drugs always die before they become blockbusters will be discussed. Dr. Van Drie will discuss examples of innovative drugs that died along the way to becoming a billion dollar blockbuster.

This event will be a great opportunity for networking and collaboration too!

Upcoming MassTERi Education Seminar:
11/17/16
Structure Activity Relationship (SAR): Moving the Goal Posts

The Diabetes Innovation Challenge Finals
Please join us for The Diabetes Innovation Challenge final project presentations.

October 20, 2016
3:30 - 8:30 pm
Royal Sonesta Boston, Cambridge, MA

RSVP now to see the final 8 presentations!

The Diabetes Innovation Challenge seeks to find transformational advancements in diabetes. The Massachusetts Medical Device Development Center (M2D2) at UMass, in partnership with T1D Exchange, a nonprofit focused on accelerating innovations that improve outcomes in type 1 diabetes, present the first Diabetes Innovation Challenge. This exciting multi-staged event is an opportunity to identify, support and incubate transformational innovations in types 1 and 2 diabetes.
You are cordially invited to attend the grand opening celebration and ribbon cutting of the Institute for Applied Life Sciences at the University of Massachusetts Amherst.

Friday, October 21, 2016
10:00 a.m. – 2:30 p.m. (reception to follow)
S330 & S340 Life Science Laboratories
3rd Floor Conference Center
240 Thatcher Road, Amherst, MA 01003

Schedule of Events

9:30 a.m. Light Breakfast and Networking
10:00 a.m. Welcome & Introductions including Chancellor Kumble R. Subbaswamy, Vice Chancellor of Research & Engagement Michael Malone, Massachusetts Senate President Stanley Rosenberg, Benjamin Bradford, Director, Regional Development Strategy, Massachusetts Life Sciences Center, Dr. Peter Reinhart, Director of the Institute for Applied Life Sciences
10:45 a.m. Ribbon Cutting
11:15 a.m. Facilities Tours & Press Interviews (including Posters & Networking Reception)
11:45 a.m. Keynote Speaker: Dr. Harvey Lodish, Professor of Biology and Founding Member, Whitehead Institute, Massachusetts Institute of Technology
12:05 p.m. IALS Vision Talks
12:35 p.m. Lunch and Facilities Tours (including Posters & Networking Reception)
1:30 p.m. Industry & Academic Collaborations Panel
   “Role of Industry in Achieving and Implementing IALS Mission/Vision”
   Moderated by: Dr. Katherine Ruiz De Luzuriaga MD, UMass Medical School
2:45 p.m. Closing Remarks followed by Facilities Tours, Posters & Networking Reception

Registration is required and space is limited. To register please go to http://www.umass.edu/ials/iams-grand-opening
For additional information or to discuss any special needs, please contact the Office of External Relations and University Events at 413.577.1101 or events@umass.edu

UMassAmherst
Inaugural Event

UNDERSTANDING & TARGETING METABOLISM IN DISEASE

MORRIE BIRNBAUM, M.D., Ph.D.
Sr. V.P. & Chief Scientific Officer
Cardiovascular and Metabolic Disease
Pfizer Incorporated

DAVID M. SABATINI, M.D., Ph.D.
Member, Whitehead Institute
Professor of Biology, MIT
Howard Hughes Medical Institute

Monday, October 24th 2016
3:00 - 5:00 PM
Sherman Center Auditorium

Hosts: David Guertin, Ph.D., Dohoon Kim, Ph.D., & Cynthia Hong, Ph.D.

Light Refreshments to Follow
Quantitative Health Sciences

QHS Special Seminar

Thursday, October 27, 2016
12:00PM – 1:00 PM

Albert Sherman Building, AS9-2072

“Measuring the Quality of Communication with Patients: How do we know what ‘quality’ is?”

Presented by: Mary Catherine Beach, MD, MPH

Mary Catherine Beach is a professor of medicine at the Johns Hopkins University School of Medicine. She holds a joint appointment in health behavior and policy at the Johns Hopkins Bloomberg School of Public Health, and is core faculty in the Berman Institute of Bioethics. Dr. Beach received her B.A. from Barnard College, her M.D. from the Mount Sinai School of Medicine, and her M.P.H. from Johns Hopkins. She has completed the Greenwall Fellowship in Bioethics and Health Policy as well as a fellowship in the Division of General Internal Medicine. In 2001, Dr. Beach was a Congressional Health Policy Fellow in the office of Senator Hillary Rodham Clinton, where she worked on issues such as patient rights, mental health parity, human subject protection, genetic discrimination, human cloning and stem cell research. She is a past recipient of the Robert Wood Johnson Generalist Physician Faculty Scholar Award and a K-88 Award from the Agency for Healthcare Research and Quality. Her research interests include health care quality for underserved populations, patient-clinician communication, and theoretical constructions of respect. Dr. Beach serves as the program director of the Predoctoral Clinical Research Training Program and course director of the Scholarly Concentrations program in the Johns Hopkins School of Medicine.

Lunch will be provided, please RSVP to Carla McDonald at carla.mcdonald@umassmed.edu

Sponsored by: UMMS Department of Quantitative Health Sciences (QHS), Health Informatics and Implementation Science Division

This MassTERi event is sponsored by the UMMS Office of Innovation and Business Development and the UMass Center for Clinical and Translational Science.
Lecture and Case Study: From Hits to Leads and Lead Optimization, the team has to choose which compounds to move forward. To do this, a relationship between a structure (i.e., a chemical modification on a compound) and an activity (potency, solubility, activity in vitro and in vivo, etc., must be understood). The SAR tables are a chemist's chart that hopefully leads him or her to the Promised Land and a molecule that will be successful clinically and commercially. Knowing when to change the criteria (the goal posts) is part of the art of making drugs. Dr. Wagner will share an example of a successful project and the SAR that drove the project.

This event will be a great opportunity for networking and collaboration too!

FUNDING and TRAINING OPPORTUNITIES

IND-Enabling Funding Award
Call for Applications

The UMass Center for Clinical and Translational Science, UMMS Innovation and Business Development, and MassBiologics of UMMS are pleased to announce a new funding opportunity to support IND/IDE-Enabling Studies. The purpose of this program is to assist faculty with the commercial development of UMass discoveries; specifically, to facilitate additional research and development work directed at enabling first in human studies.

Deadline for applications: October 24, 2016

Learn More

UMass Center for Clinical and Translational Science
Community Research Innovative Scholars Program
Call for Proposals

The Community Research Innovative Scholars Program (CRISP), from the Community Engagement and Research component of the UMass Center for Clinical and Translational Science, is pleased to offer a call for proposals to support the development of independent UMass researchers who conduct community engaged research. Community engaged research involves collaborative research with community partners along the translational research continuum.

Click here for CRISP webinar from 9/12/16.

Deadline for applications: November 1, 2016

Read More
Call for Letters of Intent

The UMass Center for Clinical and Translational Science is pleased to announce a funding call for the UMass Life Sciences Moment Fund (LSMF) 2016. The UMass LSMF supports projects that are inter-campus in orientation and directed towards life sciences projects related to clinical and translational research.

Deadline for letters of intent: November 21, 2016

Read More

UMCCTS Pilot Project Program (PPP) Call for Letters of Intent

The UMass Center for Clinical and Translational Science (UMCCTS) is announcing the next funding round for the Pilot Project Program (PPP) 2016. The intent of the funding is to speed up the rate of progress to move a research project, clinical finding or other discovery into a broader network of activities, while maximizing the breadth of transdisciplinary skills applied to the research question. We are particularly interested in proposals which feature a clinical scientist working with a basic scientist, proposals with an emphasis on community-based research, and proposals that support the career development of new investigators.

Deadline for letters of intent: November 21, 2016

Read More

UMMS Office of Global Health Pilot Project Program (OGH-PPP) Call for Letters of Intent

The UMMS Office of Global Health announces the 2017 OGH-Pilot Project Program request for proposals. The key goal of OGH-PPP funding is to catalyze the development of translational research projects that provide a firm scientific basis for clinical practice and public health policy in global settings. The intent of the OGH-PPP is to promote and prioritize for funding projects that are innovative, interdisciplinary, evidence-based, capitalize on University of Massachusetts Medical School (UMMS) programmatic strengths, and that have the best potential for future growth and external funding.

Deadline for letters of intent: November 21, 2016

Read More

Small Conference Grants are Available!

The UMass Center for Clinical and Translational Science offers Small Conference Grants (SCG) designed to leverage the convening capacity of the UMCCTS to create new, multidisciplinary teams to address a pressing health need. The conference can be a symposium, educational program, seminar, workshop or any other organized and formal meeting. The goal of the SCG is to facilitate networking opportunities between faculty that focus on clinical and translational research.

If you have an idea for an event that a SCG could help fund, visit the UMCCTS website for more information and RFA or contact Nate Hafer, PhD, Director of Operations, UMCCTS.
leadership of Drs. Catarina Kiefe and John Keaney. The program represents a wonderful opportunity for the institution to promote the entire spectrum (T0-T2+) of cardiovascular research on our campus. We are writing to request applications from trainees who wish to become part of this exciting program at the postdoctoral level. New trainees will join 4 other current trainees in the program.


Duration of support: Funding for two years of support provided. Trainees may apply for an additional year.

Amount of support: Based upon the NIH stipend schedule as outlined in the link below. Faculty sponsors may, at their discretion and with department and institutional approval supplement the NIH stipend, but only from a non-federal, non-sponsored funding source. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-048.html

Proposals are accepted on a rolling basis.

Learn More

HHMI Launches New Program for Early-Career Scientists
Hanna H. Gray Fellows Program Seeks to Enhance Diversity in Life Sciences

The Howard Hughes Medical Institute (HHMI) announces a new program to recruit and retain early-career scientists who are from gender, racial, ethnic, and other groups underrepresented in the life sciences, including those from disadvantaged backgrounds.

Deadline for applications: February 15, 2017

Learn More

Next-Gen Supply Chain QuickFire Challenge
We're Looking for the Best Biological Technology or Solution to Award 75,000 USD

At Janssen Supply Chain our goal is to deliver transformational medical solutions to people around the world. Johnson & Johnson Innovation and Janssen Supply Chain are looking to award a prize or a series of prizes to the person or team(s) who submits the best solution to key manufacturing and supply chain challenges that address the issues of higher costs and reliability in supply chains.

Deadline to apply: November 2, 2016

Learn More

The Doris Duke Charitable Foundation
2017 Clinical Scientist Development Award Competition

Pre-proposals are being sought from junior physician-scientist faculty conducting clinical research in any disease area. Competitive applicants are expected to have research experience and publication records consistent with the rank of assistant professor.

The Clinical Scientist Development Award does not require institutional nomination. This competition employs a two-stage process. Pre-proposals will be reviewed and up to 50 applicants will be invited to submit a full proposal.

Pre-proposals Due: November 29, 2016

Learn More
Antimicrobial Resistance Diagnostic Challenge

Can you help create a diagnostic tool for health care providers to better identify resistant bacterial infections?

The main purpose of the Antimicrobial Resistance Diagnostic Challenge is to incentivize the development of one or more rapid, point-of-care in vitro diagnostic tests that would be of significant clinical and public health utility to combat the development and spread of antibiotic resistant bacteria or diagnostic tests that distinguish between bacterial and viral infections.

$20 million in prize awards

Letters of Intent due December 23, 2016

Learn More

Now Open: 2017 NIH Loan Repayment Programs

The National Institutes of Health (NIH) Loan Repayment Programs (LRPs) are a set of programs established by Congress and designed to recruit and retain highly qualified health professionals into biomedical or biobehavioral research careers. The escalating costs of advanced education and training in medicine and clinical specialties are forcing some scientists to abandon their research careers for higher-paying private industry or private practice careers.

LRP is now open and will close on November 15, 2016

Read More

NIH Peer Review Online Briefings for Fellowship and R01 Grant Applicants and Basic Research Grant Applicants and Reviewers (NOT-OD-16-152)

The purpose of this Notice is to inform NIH grant applicants, their mentors, and reviewers about three online video briefings the NIH Center for Scientific Review (CSR) will host in November and December 2016. CSR is the portal for NIH grant applications and their review for scientific and technical merit.

Each Briefing Will Have a Different Focus

Fellowship and R01 grant applicants: The first two briefings will provide these applicants key information that could help them better navigate the NIH peer review process.

Basic research grant applicants and reviewers: The third briefing will reaffirm NIH’s commitment to basic research and help applicants and reviewers better do their part in proposing and reviewing basic research.

<table>
<thead>
<tr>
<th>Briefing Title</th>
<th>Date</th>
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<tbody>
<tr>
<td>8 Ways to Successfully Navigate NIH Peer Review and Get a Fellowship Grant</td>
<td>November 2, 2016</td>
</tr>
<tr>
<td>8 Ways to Successfully Navigate NIH Peer Review and Get an R01 Grant</td>
<td>December 1, 2016</td>
</tr>
<tr>
<td>NIH Peer Review Briefing for Basic Research Applicants and Reviewers</td>
<td>December 2, 2016</td>
</tr>
</tbody>
</table>

All of the briefings will run from 2:00 to about 3:00 p.m. Eastern Time, including a 30 minute Q&A period.

Read More
Harvard Catalyst is accepting applications for the next iteration of T3/T4 Research.

T3/T4 Research: Translating Effective Interventions into Practice
November 3-4, 2016
Sheraton Commander Hotel, Cambridge, MA
Tuition-free for CTSA-affiliated institutions like UMass!

This two-day introductory course offers an overview of T3/T4 research that focuses on the translation of findings from research in controlled environments to general clinical practice and population health. The goal of the T3/T4 research is to address gaps in knowledge that persist after the efficacy and safety of interventions have been defined in optimal settings. It includes studies designed to encourage the use of these interventions in routine care settings, both locally and globally, and to modify risk factors for disease.

For additional information and application details, email Harvard Catalyst today: t3t4_courses@catalyst.harvard.edu

Please remember to cite the CTSA Grant # UL1-TR001453 in all supported journal publications.

The UMass Center for Clinical and Translational Science (UMCCTS) was founded in 2006 to enhance clinical and translational research across the five University of Massachusetts campuses and our clinical partner, UMass Memorial Health Care. With the receipt of an NIH Clinical and Translational Science Award (CTSA) in 2010, and its successful renewal in 2015, the UMCCTS joined a network of 62 NIH-funded centers collaborating to transform the conduct of clinical and translational research across the U.S. Other key partners include our patients and communities, foundations, biotechnology and pharmaceutical companies, and members of the venture capital and philanthropic communities.

We encourage you to browse through our website to learn more about how the UMCCTS catalyzes clinical and translational research through education and training, pilot funding programs, cores, services and collaboration.