



## CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

October 2016 Volume 2, Issue 10

### 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](http://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](#)

**Research Career Award & Writing Group "K-Club"**  
**Join today!**



**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](#)

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#### ~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, an 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!](#)



Department of Microbiology and Physiological Systems

Presents the  
**Seventeenth Fred Fay Lecture**

2014 Nobel  
Prize Awardee  
in Chemistry



**"Nanoscopy with Focused Light"**

**Stefan W. Hell, Ph.D.**

Professor and Director  
NanoBiophotonics Department  
Max Planck Institute for Biophysical Chemistry  
Göttingen, Germany

<http://www.mpibpc.mpg.de/15045549/research>

*Tuesday, October 18, 2016*

*3:00 p.m.*

*Albert Sherman Center Auditorium*

*Rm. AS2.2102, 2<sup>nd</sup> Floor*

*Host: Ann R. Rittenhouse, Ph.D.*

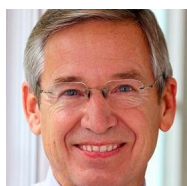
*508-856-3735*

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

**SELECTED PUBLICATIONS**

- ❖ Hell, S.W. Nanoscopy with Focused Light (Nobel Lecture). *Angew. Chem. Int. Ed. Engl.* **54**(28):8054-8066, 2015
- ❖ Lukinavicius, G., Reymond, L., Umezawa, K., Sallin, O., D'Este, E., Gottfert, F., Ta, H., Hell, S.W., Urano, Y. and Johnsson, K. Fluorogenic probes for multicolor imaging in living cells. *J. Am. Chem. Soc.* **138**(30):9365-9368, 2016
- ❖ Ta, H., Keller, J., Haltmeier, M., Saka, S.K., Schmied, J., Opazo, F., Tinnefeld, P., Munk, A. and Hell, S.W. Mapping molecules in scanning far-field fluorescence nanoscopy. *Nat. Commun.* **6**:7977 doi: 10.1038/ncomms8977 (2015).

This MassTERi event is sponsored by the UMMS Office of Innovation and Business Development and the UMass Center for Clinical and Translational Science.



**John Van Drie, PhD**

Owner and President, Van Drie Research, LLC

Pharma experience includes, BioCAD, Pharmacia, Pfizer, Vertex, Novartis

## 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\*](#)



T1D Exchange®

### 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.





IALS

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/ials-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](mailto:events@umass.edu).

UMassAmherst



UMASS **METABOLIC NETWORK**

WWW.UMASSMED.EDU/METNET

\* 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

*Sponsored by*



\* Light Refreshments to Follow



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

# 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 society at the Johns Hopkins Bloomberg School of Public Health, and is core faculty in the Berman Bioethics Institute.

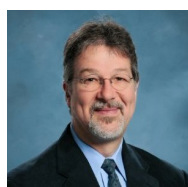
Dr. Beach received her B.A. from Barnard College, her M.D. from the Mount Sinai School of Medicine and her M.P.H. from Johns Hopkins. She has completed the Greenwall Fellowship in Bioethics and Health Policy as well as a fellowship in the Division of General Internal Medicine. In 2001, Dr. Beach was 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-08 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](mailto: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.



**Rolf Wagner, PhD**

Senior Medicinal Chemistry Group Leader, Senior Principal Research Scientist,  
AbbVie Chemistry Technologies and Outsourcing  
Pharma experience includes Hoffman-LaRoche



## Structure Activity Relationship (SAR): Moving the Goal Posts

Thursday, November 17, 2016  
AS9-2072, 9th floor conference room  
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:** 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](#)



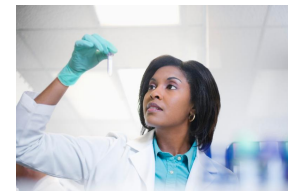
## Call for Letters of Intent

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**

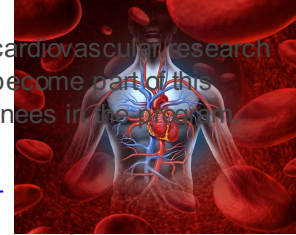
**translational research.**

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.

## University of Massachusetts Medical School Transdisciplinary Training in Cardiovascular Research (T32)

UMass has a cardiovascular T32 training grant entitled **"Transdisciplinary Training in Cardiovascular Research"** under the direction and senior

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.



**Eligibility:** Please see <http://grants.nih.gov/grants/guide/pa-files/PA-14-015.html>

**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.

Next-Gen  
Supply Chain  
**QuickFire**  
Challenge

**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.

Briefing Title	Date
8 Ways to Successfully Navigate NIH Peer Review and Get a Fellowship Grant	November 2, 2016
8 Ways to Successfully Navigate NIH Peer Review and Get an R01 Grant	December 1, 2016
NIH Peer Review Briefing for Basic Research Applicants and Reviewers	December 2, 2016

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 Course: T3/T4 Research



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



**HARVARD  
CATALYST**

THE HARVARD CLINICAL  
AND TRANSLATIONAL  
SCIENCE CENTER

### **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](mailto: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.

