Check out what's in the works!

WORKSPACE
A Cloud-Based Solution for Data Sharing and Collaboration to Advance Research and Healthcare

UMass Chan and CCTS staff (clinical researchers, data scientists, engineers, and IT professionals) are working to create a remote-access, cloud-based system called WORKSPACE where researchers can safely and compliantly access their research data virtually. Steven Wong, Director of Research Informatics Systems, says, "Investigators often struggle with the tension between safeguarding and sharing data securely with other researchers. Workspace creates a safe bubble in the cloud that facilitates collaborative research. Gone are the days when we are limited by bandwidth and hardware power because Workspace provides on-demand compute power within the data bubble while ensuring that the data is secure regardless of where you access it from." Read full details here.
**N3C Public Health Answers to Speed Tractable Results (PHASTR)**

Help address COVID questions that will have a significant impact on public health!

Accepting proposals now in the N3C Enclave!

The N3C Public Health Answers to Speed Tractable Results (PHASTR) addresses high-impact COVID-19 questions. Individuals or teams with appropriate expertise, experience, and resources can submit a proposal to answer the questions. N3C PHASTR works through a subcontract mechanism. Those with successful proposals will work through NCATS’ contractor Axle (as a subcontract) to complete the work. Additional questions will be released in the near future. Go to [https://covid.cd2h.org/phastr](https://covid.cd2h.org/phastr) to learn more.

In case you missed the PHASTR Q & A Webinar, watch it now!

New applications for other public health questions are to be released soon!

*N3C PHASTR is also funded in part by the NIH National Institute of General Medical Sciences.*

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**Events**

**H Webinar: Human Subjects Research: Policies, Clinical Trials, & Inclusion**

NIH is excited to host the

[Human Subjects Research: Policies, Clinical Trials and Inclusion event](#) on **December 6-7, 2022 (Noon-4pm ET both days).**
This event is part of a monthly deep-dive series leading up to the 2-day NIH Grants Conference (Feb 1-2, 2023). Registration is free and open to the public. One-time registration provides an All-Access Pass to all virtual events as part of the 2022-2023 NIH Grants Conference season.

Experts from the NIH Division of Human Subjects Research and HHS Office of Human Research Protections (OHRP) will share human subjects research policies, resources, guidance, and case studies in an informative and engaging, live event.

**Topics covered during this event include:**

- The basic HHS regulations and NIH policies that apply to research involving human subjects, including clinical trials.
- How to prepare a research proposal for review that addresses the regulatory requirements.
- Strategies for developing realistic and scientifically acceptable inclusion plans.

**FDA Clinical Investigator Training Course (CITC) 2022**

- Day 1: Wednesday, December 7th 11:00 am - 3:35 pm Eastern
- Day 2: Thursday, December 8th 10:55 am - 2:40 pm Eastern
ABOUT THIS CONFERENCE:
This course is designed to promote professionalism in the clinical trial industry for individuals involved with FDA submissions (Investigational New Drug (IND) Application, New Drug Application (NDA), Biologic License Application (BLA), and Investigational Device Exemption (IDE)), and to familiarize stakeholders with the regulatory and scientific issues involved in the development and approval of medical products. Participants will acquire a practical understanding of FDA’s approach to the evaluation of clinical trials, associated regulatory requirements, and other scientific issues related to investigational medical products.

TOPICS COVERED:

- Design and conduct of clinical trials
- Determining appropriate endpoints in clinical trials
- Efforts to advance diversity in trial populations
  - Statistical evaluation of clinical trials
  - Innovative trial designs
- Interpretation of the investigator brochure
- Clinical trial quality

Register: https://events-na12.adobeconnect.com/content/connect/c1/1315899612/en/events/event/shared/2657268049/event_registration.html?sco-id=5280652456&_charset_=utf-8

The Nurses Special Interest Group Speaker Series

The Nurses Special Interest Group, part of the UMCCTS, is hosting this webinar series and encourages nurse scientists, clinicians and individuals from all UMCCTS campuses and disciplines to attend.
The webinar will be presented by...

Dr. Teri Aronowitz

Circle Tied to Mother Earth:
A Culturally & Developmentally Appropriate Substance Use
Prevention Intervention for Native Youth

December 15, 2022
12:00-1:00 PM | Virtual

Dr. Aronowitz is a Professor in the Tan Chingfen Graduate School of Nursing at UMass Medical and practices at Boston University (BU) as a Nurse Practitioner in Student Health 1-day a week. Dr. Aronowitz is Editor-in-Chief of the Journal of American College Health. Her seminal contribution has been to advance the science of evidence-based care for sexual health promotion and healthy adolescent development. Dr. Aronowitz has completed over a dozen CBPR projects with African American, Asian American, Native American families to promote health adolescent development free of negative risk behaviors. She is a Fellow of the American Academy of Nursing.

Zoom
Link: https://umassmed.zoom.us/j/92957148298?pwd=RytudUFmTG80d1FhT09LVIBZdHRHUT09

Passcode: 341824
TL1 Mini-Symposium:

This event is hosted by Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS) TL1 Translation Biomedical Science (TBS) Program and co-sponsored by the Center for Leading Innovation & Collaboration (CLIC) and the William Schnaper Visiting Scientist Program (WSVS) Working Group.

Circumventing Road Blocks in Clinical and Translational Science

Registration is now open for the second virtual TL1 Visiting Scientist (William Schnaper Visiting Scientist Program) Mini-Symposium.

We invite you to join us and hear from our TL1 trainees. The goal of the virtual mini-symposium is to highlight fellows’ stories of innovation, creativity, adaptability, and including the development of new research questions and adaptation of ongoing research.

Date: Tuesday, December 13, 2022
Time: 1:00-3:00pm ET

Registration: https://georgetown.zoom.us/webinar/register/WN_GddD2C-HSnOXeHMrZXiMxQ

All TL1 pre and postdoctoral fellows, staff, and TL1 Directors are encouraged to attend and support the T’s who will be presenting.

Please contact Emily Bujold at eab159@georgetown.edu with any questions.

Effective Communication of Risk and Uncertainty With Non-Experts
Participants will learn about challenges and opportunities with respect to effective communication of risk and uncertainty, including conveyance of probabilistic information, distinguishing between absolute and relative risk, and understanding how peoples’ perceptions of uncertainty may depend on what is at stake. The focus will be on how to communicate risk and uncertainty more effectively with non-experts, including the use of visual techniques and analogies to improve understanding and uptake of information.

Justin Gross, PhD is an Associate Professor of Political Science at the University of Massachusetts Amherst as well as a core faculty member of the UMass Amherst Computational Social Science Institute (CSSI). His research interests include political ideologies, communication in mass and social media, public opinion, and the intersection of identity and political beliefs. He works on methodological problems in measurement, text analysis, and network analysis, and is especially interested in methods that put statistical and computational tools to use in service of our ability to achieve rich qualitative insights. He has taught statistical methods for over fifteen years and written about quantitative reasoning in journals and the popular press.

Real-time captioning will be provided

This is the second workshop in a 3-part series on Science Communication. The workshops are related but stand alone. You can join any or all of them, and do not need to have attended earlier sessions to take part fully in a later workshop. Watch for dates and details!

https://www.umassmed.edu/ccts/community
Grant Writing

R Club

Next Meeting

December 13th, 2022 ~ 11:00 AM -12:00 PM ~ Virtual, Zoom

Are you an early stage investigator looking to write your first R21 or R01? Would you like input and feedback on your proposal from experienced faculty who have been there before? The UMCCTS is pleased to offer the R Club, a peer group that meets twice a month to review and plan for successful R-level grant submissions. Interested? Please email nathaniel.hafer@umassmed.edu to be added to our mailing list.

Join from PC, Mac, Linux, iOS or Android: https://umassmed.zoom.us/j/5682209338?pwd=dHRmWnBnWHBZZ1I0c3B4M05Pc3BTdz09

Password: 809084
K Award Writing Group

Next Meeting

December 14th, 2022 ~ 4:00-5:00 PM ~ Virtual, Zoom

The K Award Writing Group supports junior faculty in the development of K-level "Mentored Research Scientist Career Development Award" applications. According to NIH, the award is intended to provide either progressive training or further experience in research related to biomedical, behavioral, or clinical sciences. The mentored approach provides the knowledge required for the K-Awardee to progress into an independent researcher over the award period.

K Award Group meets bi-weekly on the 2nd and 4th Wednesdays of the month from 4-5 pm via Zoom. Attendance at K Award Group meetings can be for information purposes and/or for review of your application. The group meets to outline the K-Award writing process and to review material being submitted by/to the group for input. To register to attend the K Award Group, please email Robyn.Leonard@umassmed.edu.

More Info

Funding

Funding Opportunity
NOT-AI-23-001

Notice of Special Interest (NOSI): Advance Rapid Point-of-Care Hepatitis C Virus Diagnosis

For more, check NIAID Opportunities and Announcements.
You can follow us on Twitter: @NIAIDFunding.

PAR-24-022:

Trailblazer Award for New and Early Stage Investigators
(R21 Clinical Trial Optional)

Posted Date: November 18, 2022
Application Due Dates: February 16, 2023 ongoing through October 16, 2025
(Reissue of PAR-20-084)

Award is an opportunity for NIH-defined New and Early Stage Investigators to pursue research programs that integrate engineering and the physical sciences with the life and/or biomedical sciences. Project may be exploratory, developmental, proof of concept, or high risk-high impact. No preliminary data are required.

More Info
PAR-23-025 & PAR-23-026:

Ancillary Studies to Ongoing Clinical Projects
(R01/R21 Clinical Trial Not Allowed)

Posted Date: November 21, 2022
Application Due Dates: April 6, 2023 ongoing through December 5, 2025

FOA solicits applications proposing time-sensitive ancillary studies related to the NIAMS mission in conjunction with privately or publicly funded, active, ongoing clinical parent projects (clinical trials or other active clinical studies).

More Info R01
More Info R21

PRACCTIS Program
(Prevention and Control of Cancer: Training for Change in Individuals and Systems)

The PRACCTIS program (Prevention and Control of Cancer: Training for Change in Individuals and Systems) at UMass Chan Medical School in Worcester, Massachusetts is now accepting applications for postdoctoral scholars. Funding is available starting now and in August 2023 for fellowships in three specialty areas: Cancer Prevention and Control https://bit.ly/3rzvPmt; Health Communication https://bit.ly/3Meqc6W and Tobacco and Digital Health

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Research [https://bit.ly/3D9NBUb](https://bit.ly/3D9NBUb). We train independent researchers to address critical prevention and control care delivery issues across the cancer continuum, including primary prevention, screening, diagnosis, treatment and survivorship. Emphasis is on promoting change in individuals, providers and systems. Our faculty mentors are leaders in health equity and low resource settings, health behavior change, health informatics, systems change and health policy, health communications, population health sciences, implementation science, and prevention and intervention research. Applicants must plan to pursue an independent research career focused on cancer prevention and control, have earned a doctoral degree (PhD, ScD, MD, DO, etc.), and be a U.S. citizen or permanent resident. PRACCTIS is a T32 training program funded by NCI. For more information contact Barbara Estabrook, Barbara.estabrook@umassmed.edu

Join the challenge to develop, train, and test models to aid in predicting the susceptibility to and likelihood of developing PASC/Long COVID in patients with SARS-CoV-2 infection.

Long COVID, can affect anyone, including children, and it can develop in people who had asymptomatic, mild, or severe COVID-19. To complement the National Institutes of Health (NIH) other Long COVID research initiatives, like Researching COVID to Enhance Recovery (RECOVER), the RADx-Radical (RADx-rad) program at the NIH is launching the Long COVID Computational Challenge (L3C). NIH designed this challenge to support creative data-driven solutions that meaningfully advance the current understanding of the risks of developing PASC/Long COVID.

The total prize for this Challenge will be up to $500,000.

**Submissions Due: December 15**

[Learn More](#)
RFA-AG-23-034:

Mechanism-Focused Research to Promote
Adherence to Healthful Behaviors to Prevent Mild
Cognitive Impairment (MCI) and Alzheimers Disease
(AD) and AD-Related Dementias (ADRD)
(R61/R33 Clinical Trial Required)

Closing Date for Applications: January 20, 2023

Using the R61/R33 Exploratory/Developmental Phased Award activity code, this FOA invites
applications for behavior change trials addressing psychological and interpersonal
mechanisms driving adherence to behaviors or lifestyle changes relevant to prevention of
cognitive decline, Mild Cognitive Impairment (MCI), and Alzheimer's disease (AD) and AD-related
dementias (ADRD).

RFA-AI-22-055:

Maintaining Immunity After Immunization
(U01 Clinical Trial Not Allowed)

Closing date for applications: January 13, 2023
This FOA promotes research to improve understanding of how vaccines against infectious agents lead to durable protective immunity. This initiative will support studies that define components and mechanisms of the immune system that determine such durability. Applications must propose use of human cells/tissues to decipher the human response elicited through vaccination, though animal studies may also be included.

NOT-OD-22-216 and NOT-OD-22-217:

Notices of Intent to Publish a Funding Opportunity Announcement for Development of Resources and Technologies for Enhancing Rigor, Reproducibility, and Translatability of Animal Models in Biomedical Research

(R24, R01)

Estimated FOA Publication Date: November 4, 2022
First Estimated Application Due Date: January 6, 2023
RFA-EB-22-002:

HEAL Initiative: Translational Development of Diagnostic and Therapeutic Devices
(R18 Clinical Trial Not Allowed)

Closing date for applications: June 17, 2025

This opportunity targets development of clinical-grade prototypes intended for use as safe, effective, and non-addictive device-based technologies and approaches to treat pain. Awarded activities will facilitate the translation of new devices up to the stage of readiness for first in human (FIH) clinical trials by overcoming key challenges identified during preliminary proof-of-concept studies.

More Info

NOT-OD-23-002: Notice of Special Interest (NOSI):
Administrative Supplements to Recognize Excellence in Diversity, Equity, Inclusion, and Accessibility (DEIA) Mentorship

The CCTS requests expressions of interest from individuals wishing to apply for this Administrative Supplement. Top applicants who express interest will be invited to submit full proposals. Applicants from all UMass campuses and our CCTS partner institutions are welcome to apply.

Please contact Jan Nissly with questions at Jan.Nissly@umassmed.edu.

Expressions of Interest Due to ccts@umassmed.edu by January 17, 2023.

Please include the following as a single PDF: Specific aims (1 page), NIH biosketch containing a FOA-relevant Personal Statement (5 pages max)
• Supplement is designed to support the research or mentoring career development of a scholar who has made a significant contribution to mentorship of individuals from underrepresented groups.

• The supplement PD/PI may not have more than one current independent research award.

Education & Training

UMass Chan KL2 Diversity Applicant

Request for Application (RFA)

Mentored Career Development Opportunity

The University of Massachusetts Center for Clinical and Translational Science (UMCCTS) aims to develop, support, and enhance the diversity of the next generation of leaders in clinical and translational science.
The KL2 program offers scholars with earned doctoral degrees the training, mentorship and research opportunities needed to develop a career as an independent investigator. KL2 scholars also benefit from the training programs, networking opportunities, administrative support, access to core services and pilot funding opportunities available at UMass Chan.

Current and incoming UMass Chan junior faculty members from underrepresented populations who have interest in developing an independent career in clinical and translational research are encouraged to apply.

Access KL2 Website Here

Course in Clinical Trials
Spring, 2023

Are you ready to take your molecule or intervention to the next phase of research?

The University of Massachusetts Chan Medical School (UMCMS) Graduate School of Biomedical Science is offering a course in Design and Conduct of Clinical Trials (CTS 609) in the Spring Semester 2023 (January 17-May 5). This course is open to all UMCMS research and clinical faculty, staff, students, as well as researchers external to UMCMS.

**Description:** The course is intended for the research scientist. The goal is to sharpen the methodological skills required in designing experimental studies for clinical investigators. The course will cover theoretical and practical methods in designing and implementing clinical trials, emphasizing design implications, developing individual study protocols, and addressing questions of importance in a feasible manner. The course emphasizes the design of intervention studies to achieve specific research objectives by selecting appropriate study samples, endpoints, and trial designs. It will cover not only the basics of clinical trials, including reviews/critiques of major clinical trials, but also new developments in
trial design (e.g., stepped wedge designs, adaptive designs, integrated Phase I/II and II/III designs), randomization strategies (e.g., covariate-adjusted randomizations), and trial conduct (e.g., risk-based monitoring, consent processes, difficult environments).

Dates: January 18 through May 3, 2023, no class on March 15 – Spring Break
Times: Wednesdays, 8:00 – 10:00 AM for live lectures, article reviews, and discussions
Location: Zoom

Information on how to register for the course can be found at https://www.umassmed.edu/gsbs/academic-student-affairs/registration/.

Lecturer: Dr. Bruce Barton, Professor in the Department of Population and Quantitative Health Sciences, is a biostatistician with over 45 years of experience in randomized clinical trials and has served as the Principal Investigator/Director of Data Coordinating Centers for 38 major clinical trials across all phases. Interested researchers should contact Dr. Barton (bruce.barton@umassmed.edu) for further information about the course content.

Join Us! Clinical Research Professionals Group (CRPG) Meetings

Want to know stay up-to-date about changes to regulations, research systems, and research related institutional policies around the campus?
Want to learn about the various core services that can assist you and your department in your projects and trials?

Interested in educational resources, trainings, and professional certifications?

Join us for the monthly Clinical Research Professionals Group (CRPG) meetings to hear about these topics and more!
More info, meeting schedule, and past meetings can be found on the CCTS CRPG SharePoint page.

Want to join the CRPG Distribution Group?

Submit a TRAcs request here
N3C Public Health Answers to Speed Tractable Results (PHASTR)

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Accepting proposals now in the N3C Enclave!

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In case you missed the PHASTR Q & A Webinar, watch it now!
New applications for other public health questions are to be released soon!

N3C PHASTR is also funded in part by the NIH National Institute of General Medical Sciences.

N3C In Depth CMS Training

Monday, December 12, 2022 at 9am PT / 12pm ET

Take a deeper dive into the CMS data during a live N3C CMS Webinar training that will be held on Monday, December 12 at 9am PT / 12pm ET - register here.

Through a generous grant from Assistant Secretary for Planning and Evaluation (ASPE) OS-Patient-Centered Outcomes Research Trust Fund (OS-PCORTF), the National COVID Cohort Collaborative (N3C) is pleased to announce the inclusion of de-identified linked CMS Medicare data to the existing 19
billion rows of mortality, viral variant, and clinical data in the Enclave. The addition of CMS Medicare data is an exponential leap in the scientific potential of N3C. The collaboration not only strengthens the overall capacity of the Enclave, but also resolves the issue of missing visits for patients that get their care from multiple providers.

The initial CMS data contains over 240K COVID-19 patients and will be updated on a monthly basis. The number of CMS patients represented is dependent on sites participating in the NCATS PPRL linkage initiative, and as additional sites implement the tokenization process the number of patients will increase.

Investigators registered with N3C and whose institutions have signed the NCATS Data Use Agreement will be eligible to submit a Data Use Request project proposal in the Enclave to access the CMS data.
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