



THE OHIO STATE UNIVERSITY

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

The Ohio State University Center for Clinical and Translational Science

260 Prior Hall
376 West 10th Avenue
Columbus, Ohio 43210
Tel: 614-366-5212
ccts-info@osumc.edu

The Ohio State University Center for Clinical and Translational Science (CCTS) is a collaboration among The Ohio State University, The Ohio State University Wexner Medical Center and Nationwide Children's Hospital dedicated to turning the scientific discoveries of today into life-changing disease prevention strategies and the health diagnostics and treatments of tomorrow.

Funded by a multi-year Clinical and Translational Science Award (CTSA) from the National Institutes of Health, the CCTS leverages expertise from every college across the University, including scientists and clinicians from the seven Health Science Colleges, the College of Engineering, OSU Wexner Medical Center and Nationwide Children's Hospital, community health and education agencies, business partnerships, and regional institutional network partnerships.

The CCTS provides financial, organizational, and educational support to biomedical researchers, as well as opportunities for community members to participate in credible and valuable research.

The Ohio State Center for Clinical and Translational Science (CCTS) provides research consultation services designed to help faculty, staff and service providers manage their translational research projects.

Requests for CCTS consultation services are made in the Computerized Research Record (CoRR), which is a service request system that spans across a spectrum of OSU service providers, including the CCTS, James Comprehensive Cancer Center (CCC) Shared Resources, and Department of Biomedical Informatics (BMI).

Have a question? CCTS-concierge@osumc.edu

Become a Member

The goal of the NIH CTSA program is to enhance the translation of basic science discovery to improve human health by enabling researchers to work in unprecedented ways to advance medical research.

The ability of The Ohio State University Center for Clinical and Translational Science (CCTS) to successfully meet this goal will be dependent on the engagement of the community of clinical and translational scientists at OSU to participate in educational, career development, scientific and programmatic endeavors within the CCTS.

go.osu.edu/cctsmember



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Biostatistics, Epidemiology, and Research Design (BERD) Program

BERD provides a centralized resource of expertise in the biostatistical, epidemiology and design aspects of clinical / translational, basic, and population-based research. Our group consists of a mix of faculty members and biostatisticians with expertise in a variety of areas including clinical trials, complex observational studies, and high-throughput statistical bioinformatics.

- **Navigator Model** To bolster team science, we embed biostatisticians within a research program and become involved with the research from its genesis. Navigators are intimately familiar with the clinical, biological and statistical issues related to the biomedical domain and naturally serve as point persons for establishing collaborations between these groups and the broader OSU community.
- **Workshops** We offer workshops on clinical trials and the analysis of genomics data, and are currently planning a workshop on secondary data analysis. We also provide lectures and teach courses in core areas in biostatistics, epidemiology and biomedical informatics including reproducible research.
- **Grant Preparation** We are experienced in both intramural and extramural grant submissions including NIH, DOD, AHRQ, PCORI, NSF and foundation grants and will work with investigators starting from the genesis and formulation of research hypotheses, to the design phase and sample size calculations, and finally writing a statistical analysis plan. This also includes selecting appropriate study populations and control groups, measures of exposures and outcomes, and datasets for secondary data analysis.
- **Data Analysis** Our group is experienced in the analysis of a wide variety of data including preclinical studies and biomarker discovery ('omics) approaches, complex longitudinal and cross-sectional studies, registry data, data from electronic medical records, and clinical trials. Our group will assist you with data analysis as well as interpretation and dissemination of results. Requests for analysis should be submitted through the voucher program.
- **Multidisciplinary Collaborations** BERD develops methodology in concert with our clinical, basic, and population level collaborations to promote multidisciplinary team science. These methodological advances lead to software development which facilitates practical implementation and adoption which bolsters the level of quantitative research at OSU. We have expertise which spans causal inference, genetic epidemiology, statistical genomics, metabolomics, reproductive and pediatric epidemiology, survival analysis, missing values, and clinical trials. Interested faculty members should enquire with us about planning multi-PI level grants and data coordinating centers.
- **Open Hours.** Are you interested in meeting with a biostatistician for your project but unsure about where to begin? Investigators are encouraged to drop-in with statistical questions concerning their study, e.g. to discuss study design possibilities, framing of scientific questions in a statistically testable manner, choice of statistical models / analysis techniques and sample size. Open Hours are located in the CCTS Suite 260 on Mondays: 9 am to 1pm and Thursdays: 1 pm to 5 pm.

Guy Brock, PhD

Director of BERD
Dept. of Biomedical Informatics
320N Lincoln Tower
Columbus OH 43210
614-366-8504
Guy.Brock@osumc.edu

Soledad Fernandez, PhD

Co-Director of BERD
Dept. of Biomedical Informatics
220 Lincoln Tower
Columbus OH 43210
614-293-6899
Soledad.Fernandez@osumc.edu

Research Informatics

Research Informatics is a group of highly trained software engineers, IT professionals, and biomedical informatics technicians that is a part of the Department of Biomedical Informatics. Our team leverages the skills and tools that exist within OSU's Department of BMI and OSUWMC's Information Technology Department (OSUWMC-IT) in order to provide an informatics-based catalyst in support of novel, multi-disciplinary clinical and translational science endeavors.

Research Data Capture and Access to EHR for Research

- Design data capture forms and surveys for research studies using Qualtrics or REDCap
- Facilitate research related access to data stored in OSUWMC electronic medical record system (IHIS) and Enterprise Data Warehouse system (IW)
- Provide access to i2b2 and PCORI for cohort discovery within OSU
- Design research registries using Scarlet, a registry platform that combines data from EHR, REDCap, and other custom data sources

Research Project Planning, Collaboration, and Database Consultation

- Perform informatics requirements analysis and project planning consultations
- Implement, support and facilitate access to research networking tools, including content management systems, web portals, and team-science collaboration tools
- Perform consultation on database design, optimization and development
- Facilitate the allocation of database computing and storage resources

IHIS for Research Enable novel web applications that are directly embedded inside the EHR platform

- Collaborate on prospective studies and grants to identify potential methods to leverage the EHR to collect data
- Facilitate patient to subject recruitment services through the EHR
- Design custom workflows, ensuring research compliance, data capture and efficiency

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| <p>Heather Lansky Research Data Capture Dept. of Biomedical Informatics 220 Lincoln Tower Columbus OH 43210 614-685-8504 CCTS-Informatics@osumc.edu Heather.Lansky@osumc.edu</p> | <p>Neena Thomas EHR Research Data Requests Dept. of Biomedical Informatics 650 Ackerman Rd Columbus OH 43202 614-366-5499 CCTS-IWRequests@osumc.edu Neena.Thomas@osumc.edu</p> |
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Community Engagement Services at the CCTS

The CCTS Community Engagement Program is committed to helping research teams at Ohio State and Nationwide Children's Hospital engage with their stakeholders throughout the research process, from forming a research question and study design through implementation and dissemination.

Many of our services are underwritten by the CTSA grant. Whether or not there is direct cost to you for those subsidized services, we ask that you acknowledge their value.

Request a Service <https://researchrecord.osu.edu>

Log into CoRR to create a ResearchRecord with your OSU lastname.# and password.

The Community Engagement Program is available to help research teams with:

- **Educational Opportunities** to help research team members learn the most effective ways to identify, engage with, and incorporate valuable feedback from their stakeholders.
- **Connect and Engage** with collaborative research partners across Ohio State and Nationwide Children's Hospital, and with local, regional, and statewide community partners and organizations (including Central Ohio, Southeastern Ohio/Appalachia, and OSU Extension offices across the state).
- **Cultural Competency and Dissemination** opportunities via Science Cafés, Cultural Town Halls, the Community Science Academy, and more.
- **Consultation and Feedback** from CE Program staff and our three Community Advisory Boards (Faculty, Central Ohio, and Southeast Ohio/Appalachia)
- **CE Pilot grants** through the CE Program's partnership with the OSU Connect and Collaborate Grants Program

Jeff Grever, MPH

CE Program Manager
376 West Tenth Avenue, Suite 260
Columbus OH 43210
614-366-5953
Jeff.Grever@osumc.edu

Beverly Stringer

CE Program Coordinator
Portsmouth OH
Beverly.Stringer@osumc.edu



2018-19 Connect and Collaborate Grants Program Call for Letters of Intent

Purpose. The Program incentivizes OSU-community teams to develop and grow [meaningful partnerships](#) that catalyze engaged teaching, research, and service programs with measurable and sustainable benefits to the community while advancing the strategic and scholarly goals of the university.

Grant Program Stages. The Program is a stage-gate process consisting of a Letter of Intent (LOI), pre-proposal, and full-proposal development by the applicant team, a Steering Committee, and a project development mentor. The Steering Committee and mentor contribute targeted networking and program development expertise. Working with a Steering Committee and mentor to deliver a final proposal is a required activity for all selected pre-proposals.

Funders: The Program is overseen and funded by the Stewardship Partners. The Partners establish priority focus areas; select proposals based on interest and merit; and contribute to the pool of grant funds awarded to full proposals that address their organization's priority areas. Organizations participating include: The Columbus Foundation; Greater Columbus Arts Council; Ohio Arts Council; United Way of Central Ohio; Center for Clinical and Translational Science (CCTS); Chronic Brain Injury (CBI) Discovery Theme; Corporate Engagement Office; Initiative for Food and AgriCultural Transformation (InFACT) Discovery Theme; Office of Energy and Environment/Sustainable and Resilient Economy Discovery Theme; Office of International Affairs – Global Gateways and Global One Health Initiative (GOHi); Office of Outreach and Engagement; Office of Research – Industry Liaison Office (ILO); Office of Undergraduate Education – Office of Service-Learning; OSU Extension; and OSU Wexner Medical Center.

Funding Focus Areas. Priority will be given to proposals aligning with one or more of the following areas:

- Community and Economic Development
- Education and Workforce Development
- Energy and Environment
- Food Production and Security
- Global Gateways
- Health and Wellness
- Humanities and the Arts
- One Health
- Smart Communities
- Research, Development and Commercialization

Additional information on [specific interests of Stewardship Partners is available here.](#)

Teams. Proposals must include at least one external public/private sector community partner. Partners are classified as follows: **For Profit** organizations, which exist in communities primarily to make a profit; **Non-profit** organizations, which exist primarily to provide a service to the community; and **Non-OSU Universities, Colleges, and Schools**. Programs are desirable that leverage OSU units and partnerships outside of the Columbus campus such as [OSU regional campuses](#), [OSU Extension offices](#), [OSU Centers and Institutes](#) and regional hospital partnerships.

Some Stewardship Partners have [additional team requirements](#).

Program Overview

- **Submission Process.** Eligible applicants are invited to submit a LOI that captures the essentials of the proposal using the [template](#) provided.
- **Eligibility.** LOI must be submitted by current Ohio State faculty or staff with PI status who will serve as the point of contact for communication with Connect and Collaborate and their team members during the grant program process. Final, awarded projects may have multiple leads.
- **Proposed Program Stage.** Program development occurs in three basic stages – Design, Implementation, and Expansion. Programs at or between these stages are eligible. Funding requests should be for projects that are the next logical step in advancing a program and should be commensurate with the scope and scale of the project. Proposed activities should fall within the following program development stages:
 - **Design:** Programs that are beginning with a focus on proof that the program concept has merit in terms of both value to the community and scholarship. In this stage, the needs of target population groups and program requirements are identified, program goals consistent with the missions of the university and program partners are specified, and a program that can meet these goals is crafted and assessed for value creation.
 - **Implementation:** In this stage, the initial focus is on a successful launch, then running the program in a formal fashion, but with a continual focus on improvement. New opportunities and challenges will arise – often requiring the rethinking of the program model, which will require a return to assessment activities such as feasibility and marketing studies. The outcome of implementation is an established program where products or services have come to fruition with their value reinforced through evidence of impact and demand.
 - **Expansion:** Expansion grants support scale-up or strengthening a proven program's infrastructure and capacity to produce greater impacts. The goal of expansion is to add new products or services for existing customers or expand existing offerings into new geographic regions or target populations. Because expansion 'breaks new ground' it requires planning, research, and validation of new features, which should be complementary to existing experiences and capabilities, while building on the tried and true foundation established during the implementation phase.
- **Awards and Funding.** The call for Connect and Collaborate Grants will be offered once a year with solicitations for LOI released in September. In 2017-18 the program awarded approximately \$570,000 in grants and expects to award a similar amount this year with a maximum grant award of up to \$70,000. Grant funds will be made available on a competitive basis. Duration of funding can be up to two years from the date the project is funded. Teams must plan to spend all grant funds during the specified grant period. Funds will be available no later than May 2019, but could be available earlier if full proposal/plan development is completed before the April 15, 2019 due date. The anticipated project timeline for grants awarded this year is May 1, 2019 – April 30, 2021.

- **Use of Funds.** Funds may not be used for capital improvements. Otherwise, there are no restrictions. Examples of fund use include, but are not limited to, operating costs, faculty, staff, student, and community partner support.
- **Required Cost Share.** Proposals must identify cost share at a minimum of 50% of the award amount being requested. At least half of the cost share must be cash (25% of award). Cash is defined as discretionary money that can be directly used to purchase goods and services, internal or external to the University, in support of the project. The remainder of the cost share can be in-kind contributions, a form of giving assets to the project in which goods and services are donated instead of cash.

Selection and Timeline

- **Selection Process.** LOI will be considered based on alignment with Funding Focus Areas and funding priorities of the Stewardship Partners. Teams whose LOI are selected will be invited to submit a pre-proposal (due Dec. 4). Pre-proposals will be considered on merit in addition to funding priorities of the Stewardship Partners. The highest scoring teams will be invited to present their pre-proposal to the Stewardship Partners (Jan. 29). Following presentations, the Stewardship Partners will select pre-proposals to advance to the full proposal development stage.
- Applicants will need to set aside sufficient staff time for full proposal completion. See Award Timeline for information about expected time commitments. General completion dates are provided but full proposal completion and grant awards may be expedited. Full proposals require final approval from the Stewardship Partners for funding to be released.
- **Award Timeline**

| Date | Action |
|------------------------------|--|
| Sep. 5, 2018 | Call for LOI opens |
| Sep. 13, 2018 10:00-11:00 am | Information session at The Research Commons at 18 th Avenue Library |
| Oct. 2, 2018 5:00 PM | LOI submissions due |
| Oct. 19, 2018 | Teams selected based on LOI are invited to submit pre-proposals |
| Oct. 23, 2018 10:00-11:00 am | Information session at The Research Commons at 18 th Avenue Library |
| Dec. 4, 2018 5:00 PM | Pre-proposal submissions due |
| Jan. 16, 2019 | Top tier pre-proposal teams invited to present to the Stewardship Partners |
| Jan. 29, 2019 | Presentation of top tier pre-proposals to Stewardship Partners |
| Feb. 14, 2019 | Teams selected based on pre-proposals are advanced to full proposal stage |
| Feb. 20, 2019 9:00-noon | Information session at The Research Commons at 18 th Avenue Library |
| Week of Feb. 25, 2019 | Meeting 1: Development Team (Applicant Team, Steering Committee, Mentor) |
| Week of Mar. 4, 2019 | Meeting 2 – Development Team |
| Week of Mar. 18, 2019 | Meeting 3 – Development Team |
| Week of Mar. 25, 2019 | Meeting 4 – Development Team |
| Week of Apr. 1, 2019 | Meeting 5 – Development Team |
| Week of Apr. 8, 2019 | Meeting 6 – Development Team |
| Apr. 15, 2019 5:00 PM | Full proposals due |
| May 1, 2019 | Awards made |
| May 13, 2019 | Funds available |

Application Instructions

A *complete* LOI application package consists of three sections: 1) a cover page, 2) narrative, and 3) up to three vitae/resumes of team members, no more than one page each. It is highly desired that one vitae/resume be from an external partner. Use this [template](#) to compose the LOI application.

Letter of Intent Application. As specified in the 2018-19 Letter of Intent Template, the following information is required:

Cover Page (Sections 1-7) – One Page

1. Proposal Title
2. Single Point of Contact Information
3. Program Stage (Design, Implementation, or Expansion)
4. Funding Focus Area Alignment
5. Geographic Focus
6. Type of Community Partners (For Profit; Non-profit; non-OSU Universities, Colleges and Schools)
7. Executive Summary (250-word limit)

Narrative (Sections 8-12) – One Page

8. Statement of Challenge/Opportunity
9. Approach
10. Value Proposition
11. Team Members, Internal and External (Table)
12. Budget (Table)

Vitae/Resumes – One Page per Vitae/Resume (A Maximum of 3 Vitae/Resumes)

- A. Name
- B. College / Unit / Organization
- C. Relevant Activity.

Briefly document relevant community engagement activity over the past (approximately 5) years.

- Publications, Reports, Presentations, etc.
- Funding History (Grants, etc.)
- Evidence of partnership programs (Narrative)

The cover page, narrative, and vitae/resumes must be typed in 11-point Arial or Calibri font, single-line spacing with 1-inch page margins. Charts, tables, and graphics may be used in the narrative but *will* be included as part of the one-page limit. Do not use a table of contents page or divider pages.

NOTE: LOI submissions exceeding the page limits will *not* be eligible.

The complete application package, consisting of the cover page, narrative, and vitae/resumes must be submitted as a single PDF document to engage@osu.edu no later than **5 p.m. on Tue., Oct. 2, 2018.**



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Pilot Translational & Clinical Studies Program of the CCTS

The mission of the **Pilot Translational & Clinical Studies Program** of the OSU CCTS is to fund meritorious pilot projects by cross-disciplinary teams from The Ohio State University and Nationwide Children's Hospital to: generate preliminary data, refine research strategies for subsequent extramural grant applications or to develop the best approaches, technologies and methodologies to address complex translational and clinical research problems. In addition to collaborative pilot funding programs and research development efforts, we have a new initiative for developing a new, dynamic, data-driven, multi-stakeholder framework for studying, implementing and sustaining **Innovation, Commercialization & Entrepreneurship (I.C.E.) of Clinical and Translational Research** through data analytics, institutional infrastructure and workforce development. [CCTS Pilot Programs](#) Our programs include:

- **Longitudinal Pilot Program:** To incentivize new multidisciplinary teams to translate scientific advances in incremental phases and to catalyze sustainability of the research teams and projects.
- **Collaborative Pilot Programs: PSAG, FAMEPRO, SPARC, Opioid Innovation Fund & DDI**
- **CTSA External Reviewer Exchange Consortium (CEREC):** A consortium for sharing expertise nationally to support local research by leveraging the exchange of reviewer expertise among 9 CTSA hubs to support internal pilot funding programs while minimizing conflict of interest. [CEREC website: www.icts.uci.edu/national/cerec.php](http://www.icts.uci.edu/national/cerec.php)
- **CCTS Concierge Service:** When you need help with navigating the research ecosystem, find a service, tool or a collaborator, we are happy to assist you. Log into CoRR to create a Research Record with your OSU lastname.# and password <https://researchrecord.osu.edu>
- **CCTS Information Service:** When you have a general question about the CCTS or any of our services, please use the email box CCTS-info@osumc.edu.

Reminder to Ensure Resources are available for Future Research

If you receive our pilot funds, pilot administration service or voucher support through our collaborative pilot programs, concierge and related services to support your research, please cite our CTSA grant. Awardees are required, by law, to cite the CTSA Award number on all products (publications, patents, presentations, posters) resulting from the funded project with the following: *The project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through **Grant UL1TR002733**.*

Rebecca Jackson, MD

Interim Director of PTC
376 West Tenth Avenue,
Suite 260
Columbus OH 43210
Rebecca.Jackson@osumc.edu

Bruce Weinberg, PhD

Director of CCTS I.C.E. Program
1945 N. High Street
446 Arps Hall
Columbus OH 43210
Weinberg.27@osu.edu

Tanya Mathew, BDS MS

Adminstrator of PTC and I.C.E & Concierge
376 West Tenth Avenue, Suite 260
Columbus OH 43210
614-366-5856
Tanya.Mathew@osumc.edu



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Education and Training Services at the CCTS

The OSU Center for Clinical & Translational Science has been a national leader in innovative approaches and programs in workforce development for the entire research team. Central to our workforce development efforts are training in mentoring, team science, innovation, and role-based core competencies. We offer a comprehensive series of programs and approaches to meet the lifelong career development needs for all members of the CTS workforce.

Mentored Career Development Grants

KL2 Mentored Faculty Career Development Grant. The award is designed to benefit a wide spectrum of clinical or translational researchers across OSU. The award provides salary support to ensure protected time for mentored research and didactic training in clinical/translational research across a wide variety of project topics and academic areas. The overall goal of the program is to equip early career investigators to advance from mentored to independent researchers funded by NIH RO1 grants or their equivalents.

Davis Bremer Path K Award Mentored Career Development Grant. The CCTS & OSU College of Medicine Davis Bremer Pre-K Program supports the career development of tenure and clinical track faculty in the College of Medicine who have an MD degree and who have made a commitment to conduct either patient-oriented or translational research. The Davis Bremer Pre-K Award is available for a period of two years (contingent on satisfactory progress. Applicants must be physicians credentialed by the OSU Wexner Medical Center who have Principal Investigator status.

TL1 Mentored Predoctoral and Postdoctoral Career Development Grant. The goal of the TL1 Mentored Clinical Research Training Program is to increase the number of well-trained clinician-scientists who can lead the design and oversight of future clinical investigations critical to address the nation's biomedical, behavioral, and clinical needs. It is part of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program. The TL1 award is available to: Predoctoral candidates and combined health-professional doctorate-master's candidates and to Postdoctoral trainees, including fellows and holders of research PhDs, seeking additional training in clinical research.

For more information, see the Training & Career Development page at <https://ccts.osu.edu/>

Stuart D. Hobbs, PhD, MBA

Program Director
Research Education, Training, &
Career Development
376 West Tenth Avenue, Suite 260
Columbus OH 43210
614-685-5972
Stuart.Hobbs@osumc.edu

Heather A. Mesko-Ryba

Program Coordinator
Research Education, Training, & Career
Development
376 West Tenth Avenue, Suite 260
Columbus OH 43210
614-366-3887
Heather.Mesko-Ryba@osumc.edu



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Education and Training Events from the CCTS

September 25, 2018. **Tools of the Trade: Launching Your Biomedical Research Career.** Introduction to research skills, resources, and processes; and to management and leadership skills for research. Audience: junior faculty, postdocs, and graduate students. Staff involved in the clinical research process can also benefit. **Register: go.osu/intro18**

October 9-11, 2018. **Business of Science.** Project management and leadership skills for biomedical researchers. Audience: Faculty at all levels.

October 24, 25, 2018. **Research Mentor Training.** Develop skills in mentoring early career clinical & translational sciences. Audience: Faculty at all levels.

November 6, 2018. **Tools of the Trade: Research Participant Recruitment & Retention.** Tools and best practices to promote participation in clinical research. Audience: junior faculty, postdocs, and graduate students. Staff involved in the clinical research process can also benefit.

January, 2019. **Clinical Research Boot Camp.** Basic skills and tools for conducting clinical research. Audience: Residents, Fellows, junior clinical faculty.

February 5, 2019. **Tools of the Trade: Fund Me! Publish Me!** Understanding the Grants and Manuscripts Review Process. Audience: junior faculty, postdocs, and graduate students.

April 9, 2019. **Tools of the Trade: Building a Diverse Biomedical Workforce.** Understanding the need for a diverse research workforce and funding mechanisms to help achieve this goal. Audience: Grant PIs; diversity officers; grant managers.

July 23, 2019. **Tools of the Trade: Clinical Research Topic.** Topic to be developed. Audience: Junior faculty, postdocs, and graduate students. Staff involved in the clinical research process can also benefit

2nd Tuesday of the Month. **K Lunch & Learn.** Career development and research topics. Audience: K awardees.

2nd Monday of the Month. **T Lunch & Learn.** Career development and research topics. Audience: graduate students and postdocs in NIH NRSA award programs: T32, TL1, F, etc.

See the **CCTS Calendar** at <https://ccts.osu.edu/> for specific event times and locations.

Stuart D. Hobbs, PhD, MBA

Program Director
Research Education, Training, &
Career Development
376 West Tenth Avenue, Suite 260
Columbus OH 43210
614-685-5972
Stuart.Hobbs@osumc.edu

Heather A. Mesko-Ryba

Program Coordinator
Research Education, Training, & Career
Development
376 West Tenth Avenue, Suite 260
Columbus OH 43210
614-366-3887
Heather.Mesko-Ryba@osumc.edu



NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.™

Biobehavioral Outcomes Core (BBOC) | Director: Kathryn Vannatta, PhD | 614-722-1389

The BBOC provides consultation in design of research with behavioral components; selection of appropriate behavioral measurement techniques and instruments; assistance in preparing behavioral outcomes sections of grant applications; assistance with collection, scoring, and analysis of behavioral data; assistance in preparation of manuscripts describing behavioral outcomes; identification of potential collaborators with relevant expertise; and assistance with qualitative methods, including design, execution, and approaches to data analysis

Biopathology Center (BPC) | Director: Nilsa Ramirez, MD | 614-722-2897

The BPC serves as a biorepository for projects sponsored by NCH investigators and provides a variety of services, including biospecimen processing, banking, distribution, and virtual microscopy. Visit [NationwideChildrens.org/shared-BPC](https://www.nationwidechildrens.org/shared-BPC) for more information.

Clinical Research Services (CRS) | Director: Grace Wentzel, CCRP | 614-722-2650

CRS is designed to be a portal through which clinical investigators access streamlined coordination of services necessary to initiate clinical research projects, regardless of funding source. They support all clinical research studies, providing staff and/or services to manage your study from beginning to end according to Good Clinical Practice and federal, state, and institutional regulations and guidelines. Email CRSHelps@NationwideChildrens.org or visit the CRS on Anchor.ColumbusChildrens.net/Pediatric-Research (NCH only) for more information.

Drug & Device Development Services (DDDS) | Director: Christopher Shilling, MS

DDDS assists medical faculty and investigators from pre-clinical to clinical trials, as well as guiding external partners and collaborators through the regulatory landscape. Contact Regulatory@NationwideChildrens.org or visit [NationwideChildrens.org/DDD](https://www.nationwidechildrens.org/DDD) for more information and a detailed breakdown of their services.

Intramural Funding (IMF) Program | Manager: Tiasha Letostak, PhD | 614-722-2596

Intramural grants are available to physicians, psychologists and other clinical staff at NCH if they also hold a faculty appointment at OSU. Residents and fellows may also apply. Research Institute faculty are eligible if a collaboration with a NCH clinician is proposed. For more information, please visit Anchor.ColumbusChildrens.net/CRS-Intramural-Funding (NCH only) or email IntramuralFundingOffice@NationwideChildrens.org.

Research Information Solutions and Innovation (RISI) | Director: Yungui Huang, PhD

RISI Research & Development (R&D) provides IT assistance to researchers on data processing from acquisition, curating and management to analysis and visualization, including both clinical and non-clinical basic research data. RISI R&D also bridges collaborations between internal and external researchers, researchers across centers and cores, and biostatistics, bioinformatics, mathematical and computational modeling. Visit [NationwideChildrens.org/Computational-Resources](https://www.nationwidechildrens.org/Computational-Resources) for more information.

For more information on any of these cores or other CCTS resources for NCH, email CCTS@NationwideChildrens.org.



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Participant Clinical Interactions Program & Trial Innovation Network



CCTS Participant Clinical Interactions (PCI) Program is responsible for providing facilities and resources to investigators conducting human subjects research at OSU and NCH

PCI connects investigators to local established clinical and translational research entities, leveraging collective resources and expertise

- OSU College of Medicine Clinical Trials Management Organization (CTMO)
- OSU Comprehensive Cancer Center Clinical Trials Office (CTO)
- OSU CCTS Clinical Research Center (CRC)
- NCH Clinical Research Services

PCORI and NIH proposal development services are provided through the CCTS PCI program for multicenter clinical research trials

- Study budgets
- Project management plans
- Leadership / Organizational plans
- Securing letters of support

NIH-funded Trial Innovation Network (TIN) is a new national collaborative initiative aimed at improving investigator-initiated multicenter trial operations for Clinical and Translational Science Award (CTSA) consortium members across the US - including all investigators at OSU and NCH

The TIN provides services for all aspects of proposal development and execution including:

- Efficacy to Effectiveness (E2E) consultations on clinical trial design
- Development of robust recruitment plans and materials
- Serving as a Central IRB
- Serving as a clinical and/or data coordinating center

William T. Abraham, MD

Director of PCI Program & TIN Hub
william.abraham@osumc.edu

Deanna Golden-Kreutz, PhD

Co-Director of PCI Program
deanna.golden-kreutz@osumc.edu

Angela Sow, MACPR

PCI & TIN Hub Program Manager
angela.sow@osumc.edu



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Recruitment and Retention Services at the CCTS

The goal of every research study is one that is fully recruited with high retention. In order to make that goal a possibility, research teams are encouraged to request recruitment/retention consultation early in the planning and design stages of their studies.

Many of our services are underwritten by the CTSA grant. Whether or not there is direct cost to you for those subsidized services, we ask that you acknowledge their value.

Request a Service <https://researchrecord.osu.edu>

Log into CoRR to create a ResearchRecord with your OSU lastname.# and password.

Consultation is available to help research teams with:

- **Best practices** for providing great customer service at every contact with potential and enrolled participants. (Including suggested use of **PI thank you**, **Participant Satisfaction Survey**)
- **Design** of marketing materials (brochures/flyers/postcards).
- **Referrals** from the **293-HERO** phone line and email box herohelpline@osu.edu The **HERO** line is a service that helps connect interested callers to studies for which they may be eligible. If we know about your study we can connect potential participants to you!
- **ResearchMatch** is a national volunteer registry that researchers at OSU may use to find potential volunteers at no cost. Ohio leads the nation in registered volunteers and those that have enrolled in studies via this tool. We provide assistance obtaining IRB approval to use ResearchMatch.org for recruitment and best practice tips. To get started take a look at some of the steps: <https://ccts.osu.edu/content/researchmatch>
- **StudySearch**: (<http://studysearch.osumc.edu>) was created to enhance visibility and participation in research studies conducted throughout OSU and NCH. It provides an easy way for potential study participants to find basic, descriptive information about openly recruiting research studies and trials. Researchers with an IRB approved study can submit a study within StudySearch.
- **Connecting** with the university's marketing and social media opportunities.

Tiffany Bernard

Director of Recruitment Services
ResearchMatch, Institutional Liaison
376 West Tenth Avenue, Suite 260
Columbus OH 43210
614-293-8514
Tiffany.Bernard@osumc.edu

Mary Becker

Program Coordinator, Recruitment Services
ResearchMatch, Institutional Liaison
376 West Tenth Avenue, Suite 260
Columbus OH 43210
614-293-4198
Mary.Becker@osumc.edu



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Regulatory Knowledge + Support Services at the CCTS

Navigating the federal and local regulatory landscape can be time consuming and confusing. The goal of the regulatory knowledge and support services is to advise research studies in navigating the requirements for federal and local regulations. In order to make that goal a possibility, research teams are encouraged to request regulatory consultation early in the planning and design stages of their studies.

Many of our services are underwritten by the CTSA grant. Whether or not there is direct cost to you for those subsidized services, we ask that you acknowledge their value.

Request a Service <https://researchrecord.osu.edu>

Log into CoRR to create a ResearchRecord with your OSU lastname.# and password.

Consultation is available to help research teams with:

- **Protocol and Informed Consent** review
- **Data Safety Monitoring Plans (DSMP)** design
- **Data Safety Monitoring Boards (DSMB)** conduct and administration
- **IND/IDE** submission support
- **Independent Study Safety Monitoring**
- **IRB submission review** (single and multi-center trials)
- **Regulatory Knowledge and Support Education**
 - RKS Seminar Series
 - NIH Bioethics seminar series
 - FDA conference

Rob Rengel

Regulatory Program Manager
376 West Tenth Avenue, Suite 260
Columbus OH 43210
614-366-7367
Robert.Rengel@osumc.edu



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Veterinary Clinical Research Support Shared Resource

Advancing the Health of Animals and Humans

The VCRSSR designs and conducts clinical trials in companion animals with spontaneous diseases to evaluate novel diagnostics and therapeutics and collects biospecimens, such as tissue biopsies, serum, plasma and urine, in support of comparative cancer research. The overriding goal of this resource is to advance the diagnosis and treatment of diseases in veterinary patients while enhancing the health of humans through comparative and translational studies.

About the Blue Buffalo Veterinary Clinical Trials Office

The BBVCTO was established in 2007 with the mission to advance the diagnosis and treatment of disease in veterinary patients through interdisciplinary collaborative research efforts within the CVM, OSU and NCH communities while improving the health of humans through comparative research efforts.

- Assist with protocol development
- Interface with industry sponsors
- Confirm compliance with appropriate approvals
- Formulate and review study budgets
- Conduct studies according to GCP guidelines
- Generate CRF's and data capture / REDCap
- QA/QC data
- Recruit patients through various marketing tools
- Oversee and assist with clinical trial performance
- Provide study financial management
- Collect, process, and store study samples

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| Nicole Stingle Clinical Trials Manager 614-688-5713 CTO-Clinicaltrials@osu.edu Stingle.5@osu.edu | Annie Adrian Administrative Associate 614-292-4185 CTO-Clinicaltrials@osu.edu Adrian.33@osu.edu |
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The Biospecimen Repository

The Veterinary Biospecimen Repository (VBR) is an excellent resource for therapeutic target identification and pre-clinical research. The VBR offers complete sets of tumor, normal, and blood samples as well as matched sets of primary and metastatic tumors.

The VBR is a remarkable resource that continues to assist investigators as they strive to develop new prevention and treatment strategies for both animals and people with a variety of illnesses.

Request Samples: eramp.osumc.edu

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| Holly Borghese Clinical Research Coordinator 614-292-7954 Borghese.19@osu.edu | Ohio State College of Veterinary Medicine 601 Vernon L. Tharp Street Columbus, OH 43210 vet.osu.edu/vmc/cto |
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Director: **Dr. Cheryl London**

Associate Director: **Dr. Wendy Lorch**



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CCTS Voucher Program

The OSU CCTS facilitates and supports the translation of scientific discoveries into innovations that improve health. To achieve this mission and advance translational research, the CCTS is awarding vouchers to provide funding support to investigators who require assistance from an eligible Ohio State University or Nationwide Children's Hospital core service to enable preliminary work and generate data for new or ongoing projects and/or to secure fee-based core services for expert consultation services with the ultimate goal of furthering clinical and translational research.

- Voucher requests are initiated through Computerized Research Record (CoRR) at <https://researchrecord.osu.edu/>
- Requesters must complete the intake form, which is a REDCap survey. It is sent to the requester after the voucher is requested in CoRR.
- All projects receive regulatory and science checks.
- Cores providing services are responsible for:
 - completing the cost calculation by answering the questions in the cost calc REDCap survey
 - uploading a quote or statement of work
 - sending invoices to CCTS financial personnel
- Vouchers are **not active** until all parties (PI, requester, service core, and CCTS financial personnel) have a copy of the award letter signed by the PI.
- Services invoiced to the voucher program **cannot** take place prior to the voucher award date.
- Direct all questions about the voucher program to **cctsvoucher@osumc.edu** as it is a shared inbox and monitored by multiple staff.

Request a Service <https://researchrecord.osu.edu>

Log into CoRR to create a ResearchRecord with your OSU lastname.# and password.



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Clinical Research Support

2nd Floor Dodd/Davis Hall
480 Medical Center Drive
Columbus, OH 43210
614-293-8750

With nursing, research nutrition, and laboratory support cores, **Clinical Research Center (CRC)** staff provide OSU investigators with the cutting edge tools and services needed to explore important clinical questions as well as the pathophysiology and treatment of disease.

Analytical + Specimen Processing: CRC labs provide accurate processing and analysis of samples

The Processing Laboratory provides the following services for investigators:

- Sample processing - standard and personalized
- Shipping - local and international with IATA certification
- Protocol development and support – personalized to specific needs
- Storage - short-term and for duration of in-house protocols

The Analytical + Development Laboratory provides the following services for investigators:

- Sample analysis - human, mouse, rat, canine and other animal samples
- Ultrasensitive measurement of many analytes – secreted and intracellular biomarkers including proinflammatory, cytokines, chemokines, angiogenesis, vascular injury and more
- Analytical methodologies – chemiluminescence, electrochemiluminescence, enzymatic immunoassays, chemical analysis and radioimmunoassay
- Protocol development and support - personalized to specific needs
- 24/7 monitored freezer storage
- New assay development

Contact: Trina Wemlinger, Core Laboratory Lead Technician, Clinical Research Center Ph. 614-293-7899

Research Nutrition Laboratory: Providing research nutrition, body composition, metabolic rate, and fitness resources

Nutrition and physical assessment offerings include:

- Nutrient controlled foods, meals, or menus
- Dietary Assessment & Analysis
- Body composition testing
- Counseling and education for dietary interventions
- Resting energy expenditure & substrate level oxidation
- Cardiorespiratory fitness, flexibility, and hand-strength
- Study/methods design, implementation, and evaluation services

Contact: Kristen Heitman, MS, RDN, LD, Clinical Research Dietitian, Ph.614-366-1774

Nursing + Study Implementation: CRC nursing services assist researchers and provide excellent care to research participants

CRC nurses are an integral part of successful implementation of research protocols and are experienced in caring for patients from diverse medical services, such as cardiology, endocrinology, oncology, immunology, infectious disease, neurology, nephrology, and psychiatry. The CRC delivers excellent care to all participants and ensures research visits are as comfortable and safe as possible.

CRC nurses can assist with:

- Inpatient as well as outpatient research studies of all phases
- Body measurements such as height, weight, or waist/hip measurements
- Collecting frequent times blood samples via an indwelling intravenous (IV) catheter
- Cardiac monitoring via EKG testing or continuous telemetry monitoring
- Medication administration and monitoring for side effects
- Simple blood draws
- Teaching related to study activities, medication, side effects or home specimen collection
- Point of care testing including blood sugar, HGBA1C, and pregnancy testing
- Vital sign monitoring (temperature, heart rate, respiration, blood pressure, oxygen levels)
- Invasive testing and procedures with or without conscious sedation

Contact: Holly Bookless, BSN, RN, NE-BC, Nurse Manager, Clinical Research Center, Ph.614-293-8749

Request a Service <https://researchrecord.osu.edu>

Log into CoRR to create a ResearchRecord with your OSU lastname.# and password.

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| <p>David Phillips Administrative Manager, Clinical Research Center Center for Clinical and Translational Science 614-293-4406 Office David.Phillips@osumc.edu</p> | <p>Emily Brown Office Associate Clinical Research Center Center for Clinical and Translational Science 614-293-3798 Office emily.brown@osumc.edu</p> |
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Acknowledging the CCTS

NIH requires researchers to acknowledge CTSA grant support in publications for use of CCTS services and resources

If you have accessed any services from the Ohio State University Center for Clinical and Translational Science, you are required to cite and submit the CTSA Grant UL1TR002733 with your publication.

Cite & SUBMit

Publications supported by the OSU CCTS must cite the CTSA grant number (UL1TR002733) and by law, be submitted to PubMed Central. For instructions, review the NIH Public Access Policy on the CCTS website.

UL1TR002733

For any research project that received any benefit from the CCTS (funding, use of tools, services, resources, collaborations, etc.), it is an NIH requirement to acknowledge the CTSA grant number of the institution providing support in any current or future publications. This acknowledgment is tracked and reported to the NIH and is used as a key metric for the success and continued funding of the OSU CCTS.

The language provided below is recommended for citing the CTSA grant in supported research:

CCTS services, resources, and pilot awards

The project described was supported by Award Number Grant UL1TR001070 from the National Center For Advancing Translational Sciences. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center For Advancing Translational Sciences or the National Institutes of Health.

Scholar Awards (KL2)

The project described was supported by Award Number Grant KL2TR002734 from the National Center For Advancing Translational Sciences. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center For Advancing Translational Sciences or the National Institutes of Health.

Cite & SUBMit

Publications supported by the OSU CCTS must cite the CTSA grant number (KL2TR002734) and by law, be submitted to PubMed Central. For instructions, review the NIH Public Access Policy on the CCTS website.

KL2TR002734

Trainee Awards (TL1)

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Cite & SUBMit

Publications supported by the OSU CCTS must cite the CTSA grant number (TL1TR002735) and by law, be submitted to PubMed Central. For instructions, review the NIH Public Access Policy on the CCTS website.

TL1TR002735

For non-competing continuation grant awards with a start date of July 1, 2013 or beyond: the NIH will delay the processing of an award if publications arising from it are not in compliance. When accessing the aforementioned services, please remember to cite and submit the CTSA grant UL1TR00273 with your publication.

The NIH also requires researchers to submit publications to [PubMed Central](#) for all journals that do not automatically submit them.

For more information on Cite and Submit, review the [NIH Public Access Policy](#).



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