# Office for Clinical and Translational Research (OCTR):

# **Testimonials**

### **Working with the OCTR**



"Working with the OCTR is, in essence, working with colleagues with the same vision, helping our children succeed! The quality, professionalism, team effort and friendliness of the OCTR is one of kind! We are lucky to work with such talented persons."

Sergio V. Delgado, MD Medical Director, Outpatient Services Division of Child and Adolescent Psychiatry Division of Child and Adolescent Psychiatry



"I have conducted several clinical trials using the services of the OCTR and I am very satisfied with their services.

The budget negotiations for contracts are relatively seamless. The study regulatory work and coordination are efficient. All the inpatient and outpatient components of the studies have gone well. The study team show genuine compassion toward our patients and families and are available to them during the study if problems arise. This allows me to continue my many other responsibilities in patient care, research, and teaching while still successfully offering this clinical trial opportunity to my patients. I prefer to focus on the clinical investigator portion of the research and leave the rest to the OCTR. I definitely plan to continue to use the OCTR for clinical trials."

Donald L. Gilbert, MD, MS Director, Movement Disorder Clinic and Tourette's Syndrome Clinic Division of Neurology

# **Regulatory Affairs**



"The OCTR has helped tremendously with two clinical trials that I have been involved in. Both of these trials were taken over from an investigator who left the institution, and the OCTR made the regulatory oversight of these studies seamless. I really appreciated the flexibility with which our OCTR team member helped these studies transition."

Bradley P. Dixon, MD Division of Nephrology



"OCTR regulatory staff did a very nice job of helping me with a quick turn-a-round on a PCORI grant submission last month. They did a great job of reviewing and editing the application on a tight timeline. Given that they had not seen a PCORI application before, and it was different from the standard NIH or IND applications, I was delighted to get and add their feedback and insight into my application—it helped a great deal. I have since reached out to them in anticipation of my next submission."

Richard F. Ittenbach, PhD Division of Biostatistics and Epidemiology

"The OCTR regulatory staff have seamlessly managed my multisite suicide study, including start up, IRB submissions, monitoring and support of my research staff. Trusting in their expertise has been invaluable not only because of their high quality, but mostly because it has freed me to focus on the science."

John P. Pestian, PhD, MBA Director, Computational Medicine Center Division of Biomedical Informatics



"The OCTR regulatory group has been invaluable to the Center for Pulmonary Imaging Research. In particular, they made a complicated and multistep regulatory process (filing multiple IND's with the FDA) streamlined and efficient, pointing out critical aspects of regulatory filings while handling nearly all of the paperwork. As a PI this really increased research efficiency, by allowing our efforts to be focused upon the research itself."

Jason C. Woods, PhD Director, Center for Pulmonary Imaging Research Division of Pulmonary Medicine "Cincinnati Children's Office for Clinical and Translational Research has been instrumental in helping us translate our basic research into the clinic to improve the lives of children and adults affected by rare lung diseases. Their broad-ranging support has included preparation of clinical trial, informed consent, and report documents for our IRB, submission of several IND applications and supporting documents and reports to the FDA, development of significant NIH grant funding, and the conduct and regulatory accounting of investigator-initiated, commercially-sponsored, and academic network-based clinical trials. Clearly, we would not be where we are today without their help."

Bruce C. Trapnell, MD, MS Assistant Director, Adult Cystic Fibrosis Center Co-Director, Translational Pulmonary Science Center

# **Study Start-up Team**

"I have found the Start-up Team to be very helpful and resourceful. The Start-up Team has helped us with budgets, regulatory affairs, and review of our clinical trials. We have benefited by the detailed help offered by the Start-up Team. An impartial point of view is useful when working on clinical trials."

Hannah Burke Senior Financial Analyst Division of Allergy and Immunology

# **Research Study Management**



"Though our study is relatively complex with 8 blood sample collections after painful surgery, the OCTR research nurses have done a great job doing it effectively. They are very flexible and hard working. Flexibility is important for our research as we can't reliably predict when a patient would be tolerating oral medication after surgery. Because of this positive experience with the OCTR staff, I have requested their help for another complex industry sponsored research."

Senthilkumar Sadhasivam, MD, MPH Pediatric Pain Management

# **Project Management** (Single and Multi Center Studies)



"The OCTR has been instrumental for expediting and facilitating the pre-funding planning of our multicenter proposal. From preparing budgets, to clinical protocol development, to IRB submission, and industry negotiations – it seems like the answer to all of my questions is "Yes, we would be happy to help you with that!"

Michael J. Rosen, MD, MSCI Schubert-Martin Inflammatory Bowel Disease Center Division of Gastroenterology, Hepatology, and Nutrition

# **Participant Recruitment and Retention**

"Our lab was very impressed with the resources the OCTR recruitment team was able to provide for us. We were not previously aware of all options available in terms of recruitment or outreach; they brainstormed with us and helped us cast a wide net, posting recruitment flyer pads at multiple Cincinnati Children's sites, not just our local site, and sending emails blasts to Cincinnati Children's staff at key times. They also posted flyer pads for us at sister sites like UC and it was at their suggestion that we placed an ad in Cincinnati Parent magazine, and received study interest as a result. We have a very targeted study population we are trying to recruit, and the OCTR recruitment team helped us think beyond traditional avenues of recruitment. As a result we were able to engage in the community and put the word out about our study on a much more comprehensive and successful level than we had considered possible.

Beyond recruitment, they also ensured that we maintained the high standards Cincinnati Children's is known for; working with us to design professional recruitment materials and offering suggestions on how best to interact with the public to get the word out about our study. Staff often sent us articles or community notifications they felt we may want to attend as representatives of our research team. Their consideration and hard work went a long way in helping our study."

Cameron Laue Clinical Research Coordinator III Division of Neurology



#### Participant Recruitment and Retention (continued)



"We have partnered with the OCTR recruitment team on several research studies and have found them to be responsive, professional, and creative. The OCTR team creates personalized recruitment materials and generates innovative marketing ideas which result in improved research studies and ultimately lead to better outcomes for patients and the community we serve."

Melanie F. Myers, PhD Director, Genetic Counseling Graduate Program Division of Human Genetics



"The Office for Clinical and Translational Research has been absolutely instrumental in promoting the success of our familial preterm birth studies. The have played a major role in developing the subject recruitment materials, making the effort visible to the community, and being proactive in identifying new opportunities for information dissemination. The OCTR has delivered far beyond what we had hoped for!"

Louis J. Muglia, MD, PhD Co-Director, Perinatal Institute Director, Center for Prevention of Preterm Birth Division of Neonatology

"We directly attribute the success of our study recruitment to the work of the OCTR. Without their help, we would have been limited in the scope of our recruitment and unaware of the range of resources the OCTR has to offer. Recruitment staff creativity, thoughtfulness and follow-through made participant recruitment accessible, streamlined and cohesive. The OCTR is effective and an incredibly beneficial asset to the Cincinnati Children's community."

Ernest Pedapati, MD, MS Erickson/Wink Lab



"The OCTR has been extremely helpful not only in creating marketing materials and physically helping with research subject recruitment (e.g., ensuring flyers are posted throughout the hospital), but they also have helped us to be innovative and efficient in our recruitment activities.

On numerous occasions, the OCTR has gone above and beyond the call of duty to raise the level of exposure of our Center as well as to ensure that our Center appears professional during community events."

Jeff Epstein, PhD Director, Center for ADHD Division of Behavioral Medicine and Clinical Psychology

"The OCTR recruitment team at Cincinnati Children's has been instrumental in our ability to recruit and meet enrollment goals across several projects. The Cincinnati Children's wide email blasts and well scripted radio, TV and newspaper ads allow us to access what have historically been more difficult to reach patient populations throughout Cincinnati Children's and the Cincinnati metro/tri state area."

Katie Friedmann Research Nurse II Division of Child Psychiatry



"The CyNCH recruitment materials put together by the OCTR team made our CyNCH study easier to explain to families who were considering participation and gave them something tangible to take home for consideration. It was colorful, professional and easy to read. Our national research consortium was very impressed as well by the materials and presented them as an example to the other sites of what could be done to improve recruitment. The Altered Drug Metabolism recruitment materials likewise provide a one page summary of the study that is easier for families to understand, as they consider participating. The website resulted in a spontaneous request from a family to participate, that we otherwise would have missed."

Stavra A. Xanthakos, MD, MS Co-Director, Steatohepatitis Center Medical Director, Surgical Weight Loss Program for Teens Division of Gastroenterology, Hepatology and Nutrition

# **Contact Us to Partner on Your Research:**

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# **Contracts and Budgets**

"Our experience has always been positive and the team is always responsive to questions in a timely manner. Urgent requests are positively received and acted upon. We appreciate and value the services from the budget and contract group."

Hermine Brunner, MD, MSc Division of Rheumatology and David J. Lovell, MD, MPH Associate Director Division of Rheumatology

"The OCTR contracts team has been an invaluable resource for the March of Dimes Prematurity Research Center Ohio Collaborative. As the principal coordinating site for this \$10 million March of Dimes-funded research program, Cincinnati Children's is responsible for distributing March of Dimes grant funding to the other Ohio Collaborative participating institutions. The contracts team prepares the annual subcontract agreements for each of the participating sites, working with us to assure the appropriate terms & conditions and necessary attachments are included. The team negotiates any proposed revisions with the contracting sites and follows up, as necessary, to assure all agreements are properly executed. I've had the pleasure so far to work with several members of the contracts team, all of whom conduct themselves in a professional manner and are very responsive to our needs."

Joanne Chappell
Director of Operations
March of Dimes Prematurity Research Center Ohio Collaborative



"Currently, the Center for Acute Care Nephrology has 8 or so active studies with external entities. In every instance, the OCTR contracts team has been a strong ally and advocate, highlighting areas of potential concern for me, requesting input and clarification from me, assisting me with interpretation of various issues. They are expeditious and accessible, and are proactive in contacting the external entities. It is a pleasure to work with your office."

Stuart L. Goldstein, MD, FAAP, FNKF Director, Center for Acute Care Nephrology (CACN) Medical Director, Pheresis Service Co-Medical Director, Heart Institute Research Core Division of Nephrology and Hypertension The Heart Institute

"Each experience I've had with the OCTR contracts team has been great. Not only does my division have many contracts, they are typically cumbersome to process. We work with the state of Ohio a lot and they like to send confusing contracts. The contracts team works directly with our funders to iron out contract language, invoicing requirements, and whatever odds and ends come up. They review all aspects of the contracts to be sure we can meet the requirements and do not hesitate to work on our behalf for better contract terms. They keep us in the loop and provide clarity when needed. They continually make the transition smooth for subcontracts coming in to and going out of our division."

Julie Ison Financial Analyst II James M. Anderson Center for Health Systems Excellence

"My experience with the contracts team has been very positive. They are always willing to provide guidance when setting up a contract and have been very attentive to the needs of our division. I have worked with them to resolve a contract set up issue due to an originally unknown link between two separate awards. They came to my office and we were able to review the contract together, answering questions and making comments, and determine the necessary revised contract language. This personalized approach really helped minimize confusion and provided a great start to this contract revision."

Lila Robertson Financial Analyst II Department of Neurology

"I have found the staff in the contract team to be very knowledgeable, very professional, open to questions, and willing to work with us as a team. They always run their revisions by our PI before sending them to the contracting party. I feel confident when the contract team is negotiating a contract for us that they are protecting Cincinnati Children's in all aspects of the contract, yet are willing to work with the other parties to reach a mutually agreeable agreement. They are well versed in the proper legal terminology required for our contracts. I feel that we are included and made to feel part of the negotiation process and have a great working relationship."

Patricia Holshouser Program Coordinator, Center for Acute Care Nephrology (CACN) Division of Nephrology

