Contact Us

DURING THE PLANNING PROCESS

- To help design trials to meet the needs of investigators, participants/ parents, sponsors, regulatory agencies and the institution
- To secure a confidential disclosure agreement (CDA)
- To help prepare FDA, IRB, IND and IDE submissions
- While drafting an application for a NIH funded multi-site clinical trial
- To help identify data management options and establish a plan
- To seek sponsorship for a designed trial
- To conduct a trial when contacted by a sponsor
- To coordinate a sponsor site visit for a potential trial
- To negotiate a clinical trial agreement (CTA) and budget
- To contract clinical research coordinator support, as needed
- To develop subcontracts for NIH and foundation funded clinical trials
- When planning for participant recruitment and retention, and creating recruitment and retention budgets or materials

DURING THE STUDY

- For help with study start-up and conduct
- For help scheduling site assessment or monitor visits
- When help is needed with an IRB submission or maintaining regulatory files
- To help prepare reports for the DSMB, IRB, FDA, NIH or other regulatory or funding agencies
- To help implement a data management plan
- When participant recruitment is lagging
- For temporary or permanent clinical trial support staff
- When there are general regulatory, budgetary or other study questions
- When a contract amendment is needed for any reason

AFTER THE STUDY

- To draft and edit reports and manuscripts
- To discuss successes and challenges of a completed study and plan for future studies
- To help with financial reconciliation

Cincinnati Children's®
Research Foundation

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partner with us

Office for Clinical and Translational Research (OCTR)

in your Clinical Research

Location

The OCTR is located on Cincinnati Children's Main Campus, Clinical Sciences Building (T2) next to the Schubert Research Clinic.

Contact Information

Office for Clinical and Translational Research (OCTR)

Office phone: (513) 636-3232

Fax: (513) 636-0168

OCTR@cchmc.org

Expert support for all Cincinnati Children's research:

- Pre-funding development phase planning
- NIH/Government funded trials
- Investigator-initiated clinical trials
- Pharmaceutical industry clinical trials
- Foundation/Non-Profit sponsored clinical trials
- Institutional-sponsored clinical trials

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What is the Office for Clinical and Translational Research (OCTR)?

The Office for Clinical and Translational Research is part of Cincinnati Children's Research Foundation's (CCRF) infrastructure designed to support clinical research. The OCTR's mission is to provide clinical investigators and sponsors with comprehensive support services, research tools, experienced research personnel, and facilities to conduct or facilitate pediatric and adult clinical research – from identification and development of research opportunities to phase I through phase IV clinical research trials.

Why and when should I contact the OCTR?

The OCTR functions as a "one-stop" clinical research support center – from concept development to publication.

Am I required to use the OCTR's services?

OCTR must sign all CDAs (confidential disclosure agreements), and review and approve all industry-sponsored Cincinnati Children's CSA/CTAs (clinical study agreements/clinical trial agreements) and budgets before they are accepted.

Participation in OCTR's pre-submission process for multi-site government and foundation funded trials is strongly encouraged.

The other services offered by the OCTR to support clinical studies at Cincinnati Children's are available upon request.

How much do the OCTR's services cost?

Most of the OCTR's services are supported by CCRF administration. Exceptions to this service support include:

Study Conduct
Clinical research professional coverage is available on a "fee for service" basis. The division or department and the OCTR enter into an agreement for this clinical research study support.

Participant Identification, Recruitment and Retention
The marketing and recruiting personnel services are provided at no additional cost. All advertising, promotion, printing and copying costs are handled as pass-through charges, from the outside vendors to the study business manager.

Other research services are available on a "fee for service" basis.

What services does the OCTR provide?

IDENTIFICATION AND DEVELOPMENT OF RESEARCH OPPORTUNITIES

- Development of investigator-initiated research grants and protocols
- Recruitment of industry-sponsored clinical research trials/protocols
- Protocol development consultation for industry-sponsored studies
- Protocol feasibility assessment/design
- Protocol review and approval process
- Faculty investigator identification for industry-sponsored clinical studies or multi-center studies, irrespective of funding source
- Scheduling and coordination of sponsor site assessment visits at Cincinnati Children's
- Industry sponsor identification for investigator-initiated clinical trials

CONTRACTS AND BUDGETS (FOR ALL FUNDING SOURCES)

- Execution of CDAs
- CTA facilitation as required by Cincinnati Children's Research Foundation administration
- Budget consultation, development, review, analysis and sponsor negotiation
- Institutional budgetary approval
- Financial reports and statements
- Facilitation of the contract process
- Issue, review and negotiation of NIH and foundation funded clinical trial agreements

REGULATORY AFFAIRS

- IND and IDE applications - preparation and submission
- Annual reporting as required by the FDA, IRB and DSMB
- FDA interactions and communications
- Informed consent development and submission
- IRB submissions
- Maintenance of regulatory files and subject records
- Audit preparation
- Study monitoring
- AE and SAE reporting
- Coordination of long-term document storage

PROJECT MANAGEMENT (SINGLE- AND MULTI-CENTER STUDIES)

- Investigator-initiated and industry-sponsored trials
- NIH collaborative/consortium group trials
- Rescue/rejuvenation of ongoing trials

DATA MANAGEMENT

- Collaboration with Cincinnati Children's Data Management Center for single- and multi-site trials

RESEARCH STUDY MANAGEMENT

- Investigator identification and qualification coordination
- Investigator meeting and site initiation attendance
- Central coordinating center and regulatory coordinating center for multi-site trials
- Conduct research team training: per site- and multi-center studies
- Case report forms and source documentation development
- Procedure set up with ancillary departments coordination
- Scheduling and conduct of study visits
- Contract study coordinators and research support
- Conduct of close-out activities

PARTICIPANT RECRUITMENT AND RETENTION

- Guidance and consultation for consistent and effective participant recruitment and retention practices – children and adults
- Development of strategic study recruitment and retention plans
- Construction of recruitment and retention budgets including advertising
- Creation of all print, electronic and ancillary materials including advertising and social media
- Access to the OCTR clinical research trial participant database – healthy children and adults
- Access to Cincinnati Children's clinical trials web pages, 60-plus recruitment flyer boards throughout Greater Cincinnati, as well as the semi-annual booklet of "Research Studies at Cincinnati Children's"

We provide clinical investigators and sponsors with comprehensive support services, research tools, experienced research personnel, and facilities to conduct or facilitate pediatric and adult clinical research.

INTEGRATION WITH INSTITUTIONAL RESEARCH PARTNERS

- Center for Technology Commercialization
- Biobank
- Division of Clinical Pharmacology
- Data Management Center
- Data Coordinating Center

PUBLICATION SUPPORT

- Medical writing
- Abstracts
- Publication rights and agreements