PARTNER WITH US

Office for Clinical and Translational Research (OCTR)

FOR YOUR CLINICAL RESEARCH

Cincinnati Children's™
Research Foundation

When should you 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 help prepare FDA, IRB, IND and IDE submissions
- While drafting an application for a NIH funded multi-site clinical trial
- To conduct a trial when contacted by a sponsor
- To coordinate a sponsor site visit for a potential trial
- To contract clinical research coordinator support, as needed
- When you need marketing support 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
- When participant recruitment is lagging and you need marketing services
- For temporary or permanent clinical trial support staff
- When there are general regulatory, budgetary or other study questions

After the study

- To discuss successes and challenges of a completed study and plan for future studies
- To help with financial reconciliation
- Archival of study documents

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

The OCTR 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.

Why and when should I contact the OCTR?

The OCTR functions as a "one-stop" clinical research support center — from concept development to publication. The OCTR can get involved at any point in time, but it is recommended as soon as the study team knows about the study. The OCTR can assist in the contract negotiation process as applicable.

How much do the OCTR's services cost?

Please contact the OCTR at **octr@cchmc.org.**

CLINICAL TRIALS SUPPORT

Clinical research coordinator 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.

MARKETING

Marketing services are available on a fee-for-service basis. The division or department and the OCTR enter into an agreement for this marketing support.

REGULATORY AFFAIRS

Regulatory Specialists are available on a fee-for-service basis for Investigator Initiated studies. Regulatory submissions for invoiceable fees for Industry Sponsored clinical trials should be incorporated into all Clinical Trial Agreements. Please reach out to the OCTR to ensure they are incorporated.

What services does the OCTR provide?

Identification and Development of Research Opportunities

- Recruitment of industry-sponsored clinical research trials/protocols
- Protocol feasibility assessment/design
- Protocol review and approval process
- Scheduling and coordination of sponsor site assessment visits at Cincinnati Children's
- Industry sponsor identification for investigator-initiated clinical trials

Regulatory Affairs

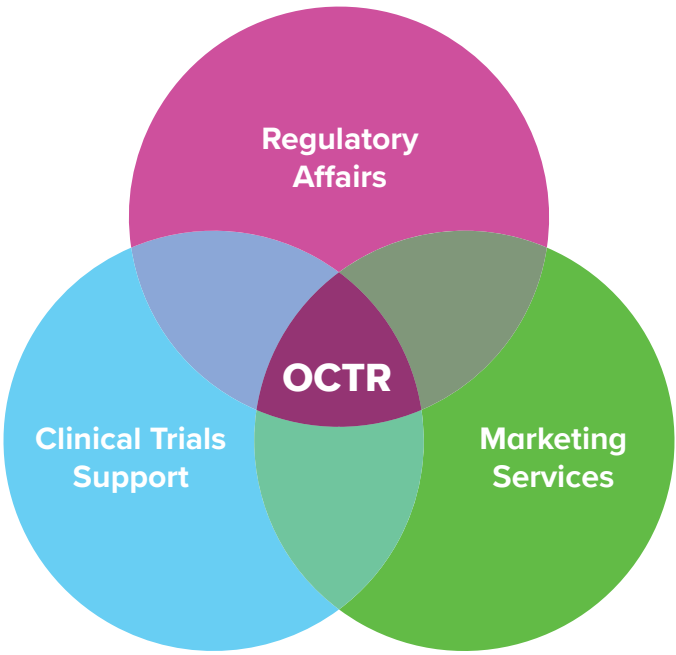
- IND and IDE applications — preparation and submission
- Annual reporting as required by the FDA, IRB and DSMB
- FDA interactions and communications
- Informed consent development and submission
- IRB submissions
- Maintenance of regulatory files and subject records
- Audit preparation
- Study monitoring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

Clinical Trials Support

- Investigator meeting and site initiation attendance
- Conduct research team training: per site and for multi-center studies
- Case report forms and source documentation development
- Procedure setup with ancillary departments' coordination
- Scheduling and conduct of study visits
- Contract study coordinators and research support
- Complete close-out activities

Marketing

- Guidance and consultation for consistent and effective participant recruitment and retention practices for children and adults
- Development of strategic study recruitment and retention plans
- Construction of recruitment and retention budgets including advertising
- Creation and execution of all print, electronic and ancillary materials including paid advertising and social media
- Access to the OCTR participant database for children and adults interested in research; study can contact potential participants and/or the study can be included in a monthly newsletter
- Inclusion on Cincinnati Children's clinical research web pages
- Inclusion on 80+ recruitment flyer boards at Main and neighborhood locations
- Inclusion in study newsletter to all Cincinnati Children's employees



Location

Cincinnati Children's Burnet Campus
3333 Burnet Ave.
Location T.2

Contact Information

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