

Accessing Research Support from CCTST

By submitting a request for support from the Center for Clinical and Translational Science and Training, investigators are able to access an array of personnel, tools and facilities to help with research.

Available support

The support available through CCTST includes:

- Biostatistical and study design consulting
- Data management tools, including REDCap and REDCap Survey
- Specialist data analytic tools
- Clinical data warehouse
- Clinical research ethics guidance
- Regulatory compliance assistance
- Pre-submission grant review
- Clinical Translational Research Center (CTRC) resources
- Participant recruitment resources
- Clinic Trials Office
- Community partnerships
- Career development guidance and grantwriting assistance
- Intramural funding opportunities

This list is illustrative only. CCTST personnel are experienced in a broad array of research and should be able to advise on the many questions or problems that arise, and identify a source for services that might be needed.

Accessing support

For assistance from the CCTST, complete a support request online at <http://cctst.uc.edu>. In the unlikely event that it is not possible to access the web site, users may e-mail CCTSTSupportRequest@cchmc.org or telephone 513-803-2920.

Requirement for consultation

It is expected that all projects supported by CCTST will require a consultation with CCTST Faculty. Faculty include specially trained researchers, methodologists and biostatisticians who work with investigators to develop a support plan that meets the needs of the individual project. This requirement for a consultation may be waived at the discretion of CCTST personnel.

What to expect at an initial consultation

Investigators should expect to meet with one of our experienced faculty, during which time we will conduct a project review and a comprehensive needs assessment. For faculty without significant research experience, including those who have not previously been a PI on an R01 or similar project, and for trainees, we request that they be accompanied by an experienced researcher who is acting as the mentor or preceptor. At the end of the initial meeting, a plan of support will be developed. In many cases, support will be provided directly by CCTST personnel. However, in some cases investigators may be referred to a specialist within our extensive network.

Timeline

After requesting support, CCTST personnel will be contacted within 3 business days. A consultation will usually be arranged within 5 business days.

If the request is for review of a protocol, manuscript or grant, initial review will usually occur within 2 weeks. For analyses or other more detailed needs, a timeline will be established at an initial meeting. The CCTST has developed timelines to help investigators plan their projects. The timelines are available online at <http://cctst.uc.edu>.

Because there are always competing demands on support, investigators are expected to work with us to help meet their deadlines. Any timelines set for providing data, providing protocol drafts, or otherwise disseminating necessary information must be strictly adhered to, or a revised timeline will need to be established.

It remains the responsibility of the investigator to ensure that all activities move forward the timeline required for the project. The CCTST will endeavor to satisfy investigators' needs, but may not be able to satisfy unrealistic deadlines.

Paying for support

The CCTST is able to offer some limited free support to investigators meeting certain criteria. Up to 10 hours of faculty support (or equivalent) per investigator per CTSA grant year may be provided at no charge for clinical and translational research that is *not* otherwise funded. After these 10 hours have been provided, investigators will be billed at current rates (for current rates, see <http://cctst.uc.edu>). For investigators with funded projects, CCTST staff will request a copy of the budget and budget justification in order to determine availability of support.

Investigators will be informed prior to incurring charges. In rare circumstances, investigators may request review of their case for access to additional free or discounted support at the CCTST T1 and T2 (TnT) meeting.

Review of projects at the CCTST T1 and T2 (TnT) meeting

Many projects have unique needs that cannot be met simply during consultancy or routine follow up. All projects may be discussed at TnT meetings to ascertain best approaches to meeting investigator needs and to identify additional opportunities for T1 and T2 translation. Projects brought to TnT will be discussed at biweekly meetings in some detail for problem solving. There may be some delay in obtaining feedback from TnT discussions because of the meeting schedule. TnT discussions will be documented in the same way as all project tracking and documentation.

Tracking and review of projects

It is the policy of CCTST to track all research projects through a database maintained by CCTST. Time and activities spent on a project are tracked, as are discussions held at the TnT meetings. On completion of projects, the record is archived.

User surveys and feedback

To meet reporting requirements and to maximize support, all investigators will be asked to provide feedback about the support they received from CCTST during the course of their project,

and are expected to do so. For most, this will be a simple web-based survey. Some investigators will be asked to participate in a short interview. These surveys and interviews are conducted by the CCTST Evaluation Core.

In addition to formal evaluation, users are encouraged to provide any feedback, either good or bad. This can be done confidentially by contacting Elizabeth Heubi (Elizabeth.Heubi@uc.edu) in the CCTST Evaluation Core. Grievances or concerns will initially be addressed by the Co-Directors of the CCTST and, if they remain unresolved, will be addressed by the CCTST Advisory Council.

Acknowledging support of the CCTST

The CCTST is funded in part by the National Institutes of Health Clinical and Translational Science Award (CTSA). All projects supported by CCTST that are being disseminated for public review must include the following text:

“This project was supported [in part] by an Institutional Clinical and Translational Science Award, NIH/NCRR Grant Number 5UL1RR026314-3. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH.”

Activities funded by other grants, such as use of REDCap should additionally acknowledge the appropriate funding source.

Inclusion of CCTST personnel on publications

It is expected that investigators will follow the International Committee of Medical Journal Editors (ICMJE) guidelines for authorship. Authors should include those who i) generate at least part of the intellectual content (conception or design, data analysis and interpretation), ii) draft, review or critically revise the manuscript for important intellectual content, and iii) approve the final version to be published. Authors should be willing and able to defend the intellectual content, including data and conclusions, concede publicly any errors and, in the case of fraud, state publicly the nature and extent, and account for its occurrence. Personnel supporting projects should be provided an opportunity to participate in publications.

Archiving publications

Investigators supported by the CCTST are required to archive all abstracts, posters and manuscripts with the CCTST.

Prioritization

Investigators should be aware that sometimes it might be necessary to prioritize a project. When this occurs, the following priority order will be used:

Priority	Function	Considerations
Highest	Access to general consultancy	Priority will be on a first come, first served basis, facilitated by the Co-Directors and Masters level biostatisticians as needed for short consultation. Lower priority will be assigned to those not developing funded research.
	Career development awards	Unfunded effort to facilitate career development awards will be provided as arranged between the trainee's primary mentor and the Biostatistics, Epidemiology and Research Design (BERD) Co-Directors.
	PHS funded projects with budget cuts	To facilitate studies that are adversely affected by budget cuts imposed during the review and funding cycle, BERD will support methodological needs to complete the program of research.
	Pilot projects, preliminary studies, and grant proposal development	Developing grant applications will generally be supported with high priority. Pilot projects supporting resubmissions close to a funding line or pilot projects designed to support new applications will be supported in preference to those without a clear long term funding plan. Projects that are not well-developed as part of (or the start of) a program of research will be supported as resources allow.
	Resident, trainee, and new investigator research	Residents, trainees and new investigators with a research mentor will be granted support (BERD faculty may be able to assist with identifying appropriate research mentors). One project will be supported for free (up to 10 hours of time, or equivalent), including design, implementation, analysis and write up. Funding will be requested for additional projects.
	Unfunded projects	Unfunded, stand-alone projects may be supported as resources allow. Novice investigators will be supported in preference to experienced investigators. Experienced investigators may be asked to pay for longitudinal support.
	Manuscripts and reports	Manuscript writing and report generation not covered by projects funds may be supported through the bridge funding mechanism unless resources are available within BERD.
	Investigator and industry-initiated funded projects	Directly supporting funded programs of research is beyond the scope of BERD. The investigator will be linked with methodologists able to support the work on a funded basis. If BERD resources are available, funded programs of research may be supported. Industry-supported projects will be supported on a fee-for-service basis since the investigator will be expected to negotiate funding for methodological support.
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