Clinical Trial Office Investigator Handbook

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Section 1: Clinical Trial Office Mission

Welcome to the Clinical Trial Office!

Our mission:
The mission of the Clinical Trial Office is to provide comprehensive contracting, budget and trial initiation services for researchers and administrators to enhance their ability to achieve excellence in the clinical trial arena while adhering to University policies. To fulfill this purpose, the office supports clinical research endeavors through study initiation, monitoring and assessment.

In carrying out these responsibilities, the office staff demonstrates a strong commitment to exceptional service and the highest professional and ethical standards to assure the Integrity of the research effort.

Section 2: List of Services Provided

Regulatory Services

The CTO provides regulatory services. Regulatory Services will include:
- Coordination of confidentiality agreements
- Preparation of any pre-selection surveys
- Site qualification visit
- Preparation of complete regulatory packet and initial IRB submission.
- Preparation and submission of Bio-Safety, and/or Radiation Safety Committee (If applicable)
- Obtain Clinical Trial Agreement (CTA)
- Coordination of activities with sponsor including Site Initiation Visit (SIV) scheduling
Budget Services
The CTO provides budget negotiation services with the sponsor on behalf of the investigator. Budget Preparation Services will include 1) assistance in contract negotiations for Industry Sponsored Studies, 2) assistance in contract negotiations for Investigator Initiated Studies with Industry Support. Generally, the following steps are managed:

** Function as liaison to:
  - Sponsored Project Services
  - University Clinical Research Center
  - Various clinical sites such as BGMC, ECMC and UBMD.
** Budget preparation and negotiation
** Monitor invoicing
** Review terms of the CTA to ensure they adhere to University policy

Other Services
Provide feasibility and needs assessments
** Meet with Principal Investigator/Study Team on a recurrent basis to review trial status and patient recruitment, identify any recruitment barriers and find solutions to overcome them
** Provide information on upcoming trial opportunities
** Mentor Program for new Investigators
** Complete Medicare coverage analysis (if applicable)
** Labor distribution
** Study Coordinator Services
** Study enrollment tracking logs/recruitment invoicing
** Internal study monitoring services

Statistical Services
These services are provided by a University biostatistician with a primary focus on Investigator initiated protocols that are applying for federal or pharmaceutical company funding. These services include:

** Methodological considerations
** Database management
** Data analysis and interpretation
** Abstract/Manuscript preparation
Proposal Development Services

Jessica Reynolds, PhD, works closely with Department of Medicine Faculty members in developing and transforming ideas into grant proposals. Some of the services may include:

- Identifying current and potential sources of funding to support programs
- Reviews and edits of grant proposals and manuscripts
- Pursuing funding opportunity databases and potential funding newsletters

Section 3: Contact Information for the CTO

Hours: Monday thru Friday 8:30 a.m.-5:00 p.m.

Contact Information:
CTO Office: 875 Ellicott Street Room 6040, Buffalo, NY 14203
Pam Anderson: 888-4841 email pka2@buffalo.edu
Jill Madden: 888-4844 email jet3@buffalo.edu

Clinical Research Center Administration:
Kim Brunton: 888-4840 email kbrunton@buffalo.edu
Cookie Thurston: 881-8911 email Thurstn@buffalo.edu

CTRC: 5th floor reception
Sheri Hosken: 888-4050 email sholsk@buffalo.edu

Building and Facilities Manager:
Rich Karalus: 888-4730 email Karalus@buffalo.edu

Security at the CTRC provided by Kaleida: 859-5441
Escort service to your vehicle: 859-5442

IRB
Training-Dorothy Wright: 829-2752 email dswright@buffalo.edu
HSIRB office: 829-2752 email hs-irb@research.buffalo.edu

University at Buffalo:
Director of HIPAA compliance- Brian Murphy: 829-3172 X2
Radiation safety officer- Jeffery Slawson: 829-3281
Statistical support- Greg Gudleski PhD. 898-6236 email Gudleski@buffalo.edu
Environment Health and Safety: 829-3301
IT assistance all requests made via email to OMC-REQ@buffalo.edu
Grant writing services- Jessica Reynolds: 888-4777 email jlr8@buffalo.edu
Section 4: Flow chart

The CTO has developed a process in which research projects will be handled within the department. Below, is a flow chart depicting this process.

The purpose of this process is to streamline how clinical research is carried out from start to finish.

Abbreviations:

CTO: Clinical Trial Office
SPS: Sponsored Program Services

CDA: Confidential Disclosure Agreement
CTA: Clinical Trial Agreement
Section 5: CDA/Feasibility

The Confidential Disclosure Agreement is usually the first form of contact from a Sponsor to an Investigator. This document must be reviewed and approved by Sponsored Program Services (SPS) before the potential Investigator receives any formal protocol from the sponsor.

Once you receive a CDA, please forward to the CTO, where we will initiate the process prior to forwarding to SPS for review and approval.

The Feasibility Questionnaire is a vital part of running a successful clinical trial. This document is sent to the PI by the sponsor and is to be completed through the CTO. This is a question/answer that will review the study’s goals and objectives versus the resources available to the PI including staffing, supplies, space requirements and patient population.

The CTO has the ability to access databases throughout affiliate institutions in order to conduct proper feasibility which allows for proper recruitment strategy evaluation.

The CTO works closely with the University’s Clinical Research Center (CRC) which will be an excellent resource to the Investigator in meeting your Clinical Trial needs.

Section 6: Regulatory documents/IRB Submission

Regulatory documents-

Sponsored research requires the use and maintenance of a regulatory binder. The CTO will complete your regulatory submission to the Sponsor on your behalf, as well as generate the regulatory binder for you through the final IRB approval.

Once your study is approved, the binder will be given to you for your use and maintenance.

IRB Submission-

As a service provided by the CTO, the documents required for your UB HSIRB, CYIRB or SBSIRB submission are prepared on your behalf. These documents include but are not limited to the Core Data Form (application), Informed consent document and HIPAA waiver.
UB IRBs utilize IRBNet for all study related administrative work. As such, all Investigators and Co-Investigators are required to register through IRBNet to electronically sign documents, submissions, receive messages, submit amendments, continuing reviews, SAEs, etc.

The CTO will submit to the IRB on your behalf and manage your submission through final approval. You will be asked to provide information as needed to ensure accuracy and completeness. You will be asked to login to the system once it has been uploaded for you, to read it over for accuracy and electronically sign it.

Documents must be received by the CTO by the 15th of the month to be submitted for the upcoming review cycle. Any submission received after the 15th of the month will be handled on a first come first serve basis and may or may not make that upcoming review cycle deadline based on workload. The submission sent to the CTO must include:

- A protocol
- Informed consent draft (non-Industry sponsored)
- Recruitment plan
- Study information form (attached)

You can register quickly at [https://www.irbnet.org/](https://www.irbnet.org/)

Once final IRB approval is received, the documents will be added to the regulatory binder and handed over for use and maintenance.

Please contact Jill Madden to get your submission started. 888-4844 email jet3@buffalo.edu

**Section 7: Budget and Contract negotiation**

One of the main functions of the CTO is budget negotiation. Budgets are always negotiable. Once the PI receives the sponsor’s budget, it should be forwarded to the CTO for the negotiation process to begin.

The goal of the CTO when developing the budget is to ensure that all costs associated
with the clinical trial receive full reimbursement. This will allow all parties to receive proper payment while supporting the research program.

During budget negotiations, the CTO will act as the liaison between the PI and the sponsor.

Please forward all budgets to Pam Anderson. 888-4841/ pka2@buffalo.edu

Section 8: Hiring study personnel

Evaluation of appropriate staffing is part of the feasibility process. Should it be identified that you will require staffing, please contact Pam Anderson at the CTO (888-4841) to set the hiring process in motion. The financial support for this will be built into your budget to cover the costs.

In addition, the CTO has Research study staff available to those investigators requiring assistance with study procedures. Once the study is recruiting, the cost for these staff will be billed to your study. This again will be built into your budget at the time of negotiation. This allows an investigator without an existing infrastructure to begin the study and actively recruit without having the funding up front. These coordinators will work on a study by study basis and be shared among divisions.

Section 9: Study initiation

Once the CTO has an approved CTA and budget as well as IRB Approval, the regulatory documents will be handed over to the PI for use and maintenance and the study team may begin their research.
Section 10: Recruitment

The CTO has access to surrounding facility databases which can be used to search for patient population to assist in study recruitment. This service will serve as an asset in recruiting and assist in meeting study objectives and goals.

Section 11: Study conduct

The PI and study team are responsible for the study conduct and adherence to the guidelines set out by the sponsor. However; the CTO will offer assistance where requested with invoicing, statistical analysis support as well as database review for patient recruitment purposes.

The CTO will meet with the investigator and/or study team on a quarterly basis to review study progress and recruitment to see if new strategies or opportunities should be considered. In addition, review of study enrollment logs will be conducted to ensure all costs are recovered from the sponsor.

If you believe you need assistance in any of these areas, please contact the CTO.

Section 12: Study Closure

Once the study is ready for closure, the PI will contact the CTO in order to confirm that all study payments have been received. Additionally, the Clinical Trial Agreement and the budget will be reconciled to ensure all fees have been reimbursed including any hold backs.
Section 13: Helpful Links

Local links:

http://www.research.buffalo.edu

http://www.research.buffalo.edu/rsp/irb/hsirb/

http://medicine.buffalo.edu/departments/medicine.html

www.irbnet.org

www.citiprogram.org

https://www.researchmatch.org/

http://www.buffaloctrp.org/

http://www.research.buffalo.edu/compliance/coi/riskmanager.cfm

Other helpful links:

http://www.clinicaltrials.gov/

http://www.nih.gov/


http://www.fda.gov/