Welcome to CCTS!

UAB serves as the “Hub” for the CCTS Partner Network, which is funded by the National Center for Advancing Translational Sciences (NCATS) at NIH. As one of more than 50 such centers across the country, the CCTS offers you a wealth of resources to help advance your science and your career. As a member, you will receive our weekly e-newsletter, **CCTS Digest**, which highlights the latest clinical and translational science news, events, trainings, and funding announcements.

Here are just a few of the many supports available to you through the CCTS:

- Multisite study opportunities via SHARE, TriNetX, and other CCTS partnerships
- Advanced proposal reviews by a team of experts via Project Panels
- Skills-building trainings, like our popular Accessing Clinical Data for Research with i2b2
- Special funding opportunities, including our CCTS Interdisciplinary Network Pilot Program and Research Vouchers
- Regulatory expertise to guide you in meeting the latest federal research policies, such as the NIH ClinicalTrials.gov and Good Clinical Practice (GCP) requirements
- Methodological expertise to ensure your grants meet NIH Rigor, Reproducibility, and Transparency (R2T) review criteria
- Samples of successfully funded NIH, NSF, DoD, and foundation grant applications in our Grant Library
- Biomedical informatics and data analysis support and collaboration
- Entrepreneurial workshops based on NSF I-Corps™ Lean Startup Methodology
- Drop-in clinics and consultations with experts from our Bionutrition, Biorepository, Clinical Research and BERD (Biostatistics, Epidemiology, and Research Design) units
- Research training fellowships and certificate programs for professional development across the career arc
- Community-based research events and programs
- A wealth of cutting-edge knowledge free for the watching on our CCTS YouTube channel

The CCTS is here for you. We look forward to working together to enhance the translation of basic and clinical research into improvements for human health and health care delivery.
Key Websites for Clinical Trialists

ACT Network
http://www.actnetwork.us/National

Clinical Trails Administrative Office (CTAO)
https://www.uab.edu/ccts/clinical-translation/clinical-services/ctao
https://www.uab.edu/medicine/ctao/

Forte OnCore
https://forteresearch.com/enterprise-research-oncore/
https://www.uab.edu/ccts/clinical-translation/clinical-services/ctao/oncore

i2b2
https://www.uab.edu/ccts/research-commons/informatics/i2b2

Office of the Vice President of Research (OVPR)
https://www.uab.edu/research/administration/Pages/Home.aspx

The Southeast Health Alliance for Research (SHARE)
https://www.uab.edu/ccts/partnerships/share

Trial Innovation Network (TIN)
https://ncats.nih.gov/ctsa/projects/network
https://www.uab.edu/ccts/partnerships/collaborative-platforms/trial-innovation-network

TriNetX
https://www.uab.edu/ccts/partnerships/collaborative-platforms/trinetx

UAB Medicine Clinical Trials Search
https://www.xpertdox.com/uab-trial
CTTI Recommendations: Identifying Qualified Investigators and Their Delegates to Conduct Sponsored Clinical Trials

November 2018

CTTI MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

OVERVIEW: Finding Value in Investigator Qualification

These recommendations are based on expert consensus and are intended to help sponsors, contract research organizations (CROs), and site teams better identify qualified investigators and their delegates to conduct clinical trials. This new approach to "qualification" goes beyond repetitive one-size-fits-all training to include individual experience and protocol-specific preparation. CTTI's recommendations address how to:

- Implement a more efficient and effective means of qualification,
- Determine whether a site team is a good fit for a particular protocol, and
- Improve the quality conduct of clinical trials.

The Challenge

The FDA regulations for clinical trials state that sponsors are responsible for "selecting investigators qualified by training and experience," and this requirement extends to delegated members of the site team (aka delegates). However, the regulations do not provide guidelines for how to meet this requirement.

Although FDA regulations do not specify Good Clinical Practice (GCP) training, it is widely used as the industry standard for ensuring investigators are qualified. Therefore, sponsors generally require investigators and their delegates to complete GCP training before every clinical trial they conduct, regardless of their prior training and experience.

There is little evidence that completion of GCP training alone sufficiently qualifies investigators and their delegates to conduct quality clinical trials. In fact, the most common deficiencies noted during investigator inspections are directly related to GCP principles. Furthermore, redundant training creates an unnecessary burden for site teams and limits the opportunity for more valuable, protocol-specific learning and preparation.

---

a Sponsors are responsible for selecting qualified investigators, per 21 CFR 312.50 and 312.53(a) for drugs and biologics and 21 CFR 812.40 and 812.43(a) for medical devices.

b References to "investigators and delegates" and "site teams" are used interchangeably throughout this document.
CTTI's Solution

To address this challenge, CTTI sought input from a multi-stakeholder team of experts to develop the following recommendations on how to identify qualified investigators and their delegates while simultaneously reducing inefficiencies in training and better preparing for the quality conduct of clinical trials.  

"Qualification" and "preparation" are often viewed as separate concepts. Here, we treat them as two sides of the same coin: If investigators and their delegates are appropriately prepared for a trial, then they are qualified to conduct it.

This shift will depend upon

1. Investigators and their delegates assuming greater control of their qualification, and
2. Sponsors and CROs being willing to accept documentation of relevant education and experience as evidence that investigators and their delegates are qualified

A NEW APPROACH TO IDENTIFYING QUALIFIED INVESTIGATORS AND THEIR DELEGATES

- A move away from repetitive GCP training as the one-size-fits-all approach to qualifying investigators and their delegates for the conduct of clinical trials
- A step toward targeted and effective educational programming, with less redundant and burdensome training
- A shift in the perception of qualification activities from "necessary but low value" to "an opportunity for improved quality and efficiency"
- Recognition of previous training and experience that supports the transfer of skills between studies
- Identification of gaps in knowledge or skills that are then addressed using innovative and constructive adult learning methods
- Improved understanding of how to apply GCP principles to the conduct of clinical trials

---

\(^c\) Institutional review boards (IRBs) may also benefit from these recommendations in fulfilling their regulatory requirement to evaluate investigator qualifications, per 21 CFR 56.107(a).
To support the implementation of these expert-based recommendations, CTTI has developed a framework of characteristics to help sponsors, CROs, and site teams assess whether investigators and their delegates are qualified to conduct a particular trial. Freely adapt this framework as necessary to meet the unique needs of the site team and protocol under consideration. Site teams can also use this tool to evaluate their general preparedness for any trial.

**ANTICIPATED IMPACT OF IMPLEMENTING THESE RECOMMENDATIONS**

- A **culture of collaboration** between sponsors, CROs, and site teams in preparing investigators and their delegates to conduct clinical trials
- **Improved execution of study protocol** as sponsors and investigators are able to allocate more time to protocol-specific concerns
- **Fewer regulatory findings** related to GCP elements
- **Improved quality**, including better data, fewer queries and protocol deviations, and improved study participant safety
- **Improved efficiency**, including shorter recruitment timelines, improved study participant retention, and less time spent resolving discrepancies
- **Ongoing support and communication through formalized mentorship and knowledge-sharing platforms**

Successful clinical trials require a well-designed protocol and robust site-based research infrastructure in addition to well-qualified site teams. Therefore, we suggest you use these recommendations on qualifying site teams in conjunction with (1) CTTI’s **Quality by Design recommendations** on protocol development and (2) CTTI’s **Investigator Community recommendations** for a holistic approach to conducting quality clinical trials.
CONTENTS AT-A-GLANCE

Investigator Qualification Recommendations

- Quality Conduct by Design
- Improving Educational Offerings

Investigator Qualification Resources

- Framework of Characteristics of a Qualified Site Team: How Does Yours Measure Up?
- Documenting Qualification: A Quick Reference Guide for Investigators and their Delegates
- Documentation Template
- Appendix 1: Resources for Training and Learning
- Appendix 2: Mentoring and Knowledge-Sharing Examples

Other Relevant CTTI Recommendations

- Quality by Design
- Investigator Community
- Good Clinical Practice (GCP) Training for Investigators
I. Quality Conduct by Design

Quality by design (QbD) principles\(^2\) should be used to provide an effective, proactive framework for developing protocols that operate efficiently, adequately safeguard study participants, and produce credible and accurate information. Likewise, QbD can provide a practical, outcomes-focused approach to the identification of qualified investigators and their delegates.\(^d\)

1. Expand qualification beyond GCP training

Completion of GCP training alone is insufficient to qualify investigators and their delegates for the quality conduct of clinical trials. Although the training covers principles that are critical to the credibility and accuracy of trial data and the protection of human subjects, repetitive didactic\(^e\) presentation of GCP elements is unlikely to either:

- Adequately prepare an inexperienced member of a site team, or
- Add value to the practice of an experienced researcher.

CTTI’s recommendations on **GCP Training for Investigators** describe how to optimize GCP training where members of the site team may still need education on applying GCP elements. However, those investigators and delegates who regularly demonstrate proficiency in applying GCP elements should be exempt from further GCP training requirements.

**Recommendations for Sponsors and CROs**

---

\(^d\) This approach is also consistent with the renovations to the International Council for Harmonization (ICH) E6 guidelines on GCP that promote flexibility in managing risk during the conduct of clinical trials.

\(^e\) Didactic learning describes instructor-led communication of theoretical knowledge.
Move away from repetitive GCP training as the one-size-fits-all approach to qualifying investigators and their delegates for the conduct of clinical trials.

Instead of repeating the standard one-size-fits-all training at the start of each study, develop educational programming that is tailored to your protocol and the members of your site team, as outlined in Section III, Improving Educational Programming.

Recommendations for Investigators and Their Delegates

- Recognize that completion of GCP training in isolation is insufficient to fully prepare for the quality conduct of a clinical trial.

- Evaluate your site team's preparedness to conduct clinical research before seeking selection as a trial site. To guide this assessment, CTTI has developed a framework of characteristics describing attributes that are within your control and can be modified through learning and training.

2. Identify the unique learning requirements of each trial

The knowledge, skills, and experience required for investigators and their delegates will vary with each trial. Different study phases, disease states, protocol designs, study participant populations, and clinical settings guide unique requirements.

Recommendations for Sponsors and CROs

- To support investigators in their assessment of their ability to conduct a given study protocol and identify any learning requirements, provide the completed or draft protocol to potential site teams at the beginning of the site selection process. Such transparency is crucial to establishing a collaborative approach to identifying qualified investigators and their delegates.

- Allow site teams to review and provide feedback on the protocol to help address potential feasibility issues or concerns up front. In addition, these site teams will better understand the protocol requirements once the study begins. This exchange of information is a critical part of the learning necessary for each new protocol and engages the site team in a way that didactic instruction does not.

- Complete thorough pre-study visits. CTTI has developed a framework of characteristics to help guide the assessment and selection of sites.

Recommendations for Investigators and Their Delegates

- To prepare for a specific trial:
• Request the full protocol—even if only in draft—as soon as you are contacted about a trial, and

• Assess whether you and your delegates are adequately qualified to conduct the trial. CTTI has developed a framework of characteristics to help guide this assessment.

Discuss your assessment findings openly with the sponsor to close any gaps in preparedness. Such transparency and collaboration are necessary to ensure that the educational resources available through the sponsor are used in support of the site team’s efforts to meet the specific needs of a given protocol.

3. Take a targeted approach to being qualified

A targeted, risk-based approach to being qualified involves (1) identifying potential high risks in protocol execution and (2) focusing targeted, applied learning solutions toward these high-risk areas. Risk analyses should not only consider potential challenges associated with a given protocol, but also reflect the most common deviations experienced by site teams on protocols similar in design or therapeutic area.

Recommendations for Sponsors and CROs

• Critically evaluate the skills, knowledge, and experience of site teams before (1) site selection and (2) formulation of learning requirements. CTTI has developed a framework of characteristics to help guide this evaluation.

• Discuss your evaluation of the site openly with investigators. Transparency surrounding your assessment of a site team’s ability to satisfy the requirements of a particular protocol is critical for identifying educational needs and creating appropriate educational programming to ensure that investigators and their delegates are truly qualified.

• Consider reallocating resources to identifying qualified investigators and their delegates as needed. Investing time and effort toward site selection and preparation can preempt quality issues and avoid the need to invest additional resources to fix them.

Recommendations for Investigators and Their Delegates

• Consider your performance on past protocols to develop policies, procedures, or educational programming to improve the conduct of future studies. For example, reviewing common protocol deviations may allow you to create strategies to avoid such deficiencies. Analyses of recruitment and enrollment efforts may identify tactics that have worked, as well as areas that need improvement. Once addressed, you can focus on closing gaps that come up on a study-by-study basis. CTTI has developed a framework of characteristics to help guide this
assessment, and Appendix 1 provides an inventory of resources for training and learning.

- Share your findings with sponsors and CROs during the site selection process to guide effective preparation of the site team.

II. Improving Educational Offerings

1. Create educational programming with adult learners in mind, taking into account individual study roles

To ensure investigators and their delegates are qualified, educational programming should focus on the learning requirements of the specific trial and address the gaps in knowledge and skills identified in Section I, Quality Conduct by Design.

Active learning encompasses a broad range of unstructured/informal and structured/formal approaches to increasing knowledge and skills.

Training is one type of learning that imparts information through a structured, learner-centered approach with measurable outcomes.

Site-based learning activities may include:

- Mentoring programs,
- Job-shadowing programs,
- Virtual or in-person knowledge-sharing networks,¹ and
- Mock run-throughs of study participant visits and protocol procedures.

¹ A knowledge-sharing network is a collection of individuals and teams who come together across organizational, spatial, and disciplinary boundaries to create and share a body of knowledge.
These activities are based on established adult learning methods (see box at right). CTTI has compiled a compendium of existing mentoring programs and knowledge-sharing networks to illustrate how these activities are being implemented in practice (see Appendix 2).

**Recommendations for Sponsors and CROs**

**What is adult learning?**

- **Self-directed:** Empowers the learner to diagnose learning needs and formulate goals
- **Experience-based:** Leverages professional experience when introducing new material
- **Goal-oriented:** Times the delivery of information so that the learner may soon apply the skill during a trial
- **Relevant:** Emphasizes why practices are recommended or required
- **Practical:** Focuses on application of knowledge, concepts, and skills
- **Collaborative:** Creates a partnership between the learner and the instructor

Adapted from 'Malcolm Knowles' Adult Learning Theory

- Recognize the value in learning approaches that go beyond traditional training methods. Consider establishing knowledge-sharing networks for specific trials, which provide forums for information exchange and peer support (see Appendix 2).

- Accept documentation of (1) the completion of previous relevant training, and/or (2) the continued application of knowledge and skills during the conduct of clinical trials as evidence that investigators and their delegates are qualified (see CTTI’s Quick Reference Guide to Documenting Qualification for Investigators and Their Delegates and the documentation template).

- Consider the previous application of required skills when tailoring protocol-specific educational programming to meet individual learning needs.

- Apply adult learning approaches when developing educational programming.

- Clearly define gaps in knowledge and skills as you consider the learning requirements for a study, and develop educational programming to address them. CTTI has developed a framework of characteristics to help identify learning goals.

- Create role- and protocol-specific education goals that communicate what is new, unique, and difficult about the study to assess and manage risk.

- Recognize that different members of the site team may benefit from different types of education and experience in pursuit of the same learning goal.
Recommendations for Investigators and Their Delegates

- Consider how to best meet your learning goals, including through approaches other than traditional training as described above. See Appendix 2 for specific examples.

- Seek out educational offerings that meet content-specific learning goals and suit individual learning styles. Time the completion of educational programming to coincide with conducting trial activities that require the knowledge and skills learned.

- Encourage more experienced members of the site team to participate in mentoring programs with less experienced members.

- Document learning activities, as well as the successful application of knowledge and skills pertinent to your role in conducting trials, to serve as a record demonstrating your qualification for the conduct of clinical trials. CTTI has developed a Quick Reference Guide to Documenting Qualification for Investigators and Their Delegates and a documentation template for recording this information.

REFERENCES


ABOUT THE RECOMMENDATIONS

- These recommendations are based on results from CTTI's Investigator Qualification Project.

- CTTI's Executive Committee approved on Sept. 24, 2018.

- Funding for this work was made possible, in part, by the Food and Drug Administration through grant R18FD005292 and cooperative agreement U19FD003800. Views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government. Partial funding was also provided by pooled membership fees from CTTI's member organizations.
All of **CTTI's official recommendations** are publicly available. Use of the recommendations is encouraged with **appropriate citation**.

**ABOUT CTTI**

Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Comprised of more than 80 member organizations—representing academia, clinical investigators, government and regulatory agencies, industry, institutional review boards, patient advocacy groups, and other groups—CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges. Many regulatory agencies and organizations have applied CTTI's nearly 20 existing recommendations, and associated resources, to make better clinical trials a reality. Learn more about CTTI projects, recommendations, and resources at [www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org).
THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

MEMORANDUM

TO: University Deans, Chairs, Faculty, & Staff

FROM: Selwyn M. Vickers, MD, Senior Vice President for Medicine and Dean, School of Medicine
       Christopher S. Brown, PhD, Vice President for Research
       Robert P. Kimberly, MD, Senior Associate Dean for Clinical and Translational Research, School of Medicine

DATE: February 1, 2019

SUBJECT: Study Management Fee for Industry-Initiated and Sponsored Clinical Trial Budgets

Effective February 15, 2019, all industry-initiated and sponsored clinical trial budgets will be required to include a non-negotiable Study Management Fee of $4,500 for trials reviewed by an outside IRB (such as WIRB) or $5,500 for those reviewed by the UAB IRB.

This Study Management Fee subsumes the UAB Human Subjects Review Fee previously charged for industry-initiated and sponsored protocols and reflects the costs associated with supporting operations related to the conduct of clinical trials on campus. These operations include:

- Review for the Protection of Human Subjects (IRB);
- Review of Financial Interests by Responsible Personnel (CIRB);
- Medicare Coverage Analysis (CIR); and
- Study Management Software (OnCore/PowerTrials).

After the initial year of each study, an annual Study Maintenance Fee of $1,000 will commence in 2020 to support the costs of the Clinical Trial Administrative Office, including CBR and OnCore/PowerTrials. Both the Study Management Fee and the Study Maintenance Fee are subject to the applicable F&A rate.

If you have any questions, you may contact Mark Marchant, Director of the Clinical Trials Administrative Office, at 205-934-2098 or marchant@uab.edu.
Fees Charged by UAB for Industry-Initiated and Sponsored Protocols

Study Management Fee

Effective February 15, 2019, all industry-initiated and sponsored clinical trial agreements will be assessed a non-negotiable Study Management Fee. The fee is $5,500 or $4,500 (see below*). It is separate from any applicable Department-specific fees associated with conducting the trial. Beginning in January 2020, UAB will also charge a Study Maintenance Fee of $1,000 annually for ongoing trials. The annual Study Maintenance Fee is due each year on the anniversary date of the study’s initial submission to the OIRB and is applicable until the study is in a status of Completed with the UAB OIRB.

The Study Management Fee addresses costs associated with reviews and work conducted on industry-initiated and sponsored protocols by several areas involved in the activation process which includes the following:

- The Office of the Institutional Review Board (IRB) performs a pre-review of the protocol for institutional and WIRB requirements and stores, maintains, and updates the file through the life of the protocol at UAB. If applicable, the UAB IRB will conduct an expedited or full review.

- The Office of the Conflict of Interest Review Board (OCIRB) must review the responsible personnel on the project and their associated financial interests to ensure any conflicts that may exist are managed appropriately. These reviews occur as needed throughout the life of the protocol at UAB.

- The Clinical Billing Review (CBR) unit of the Clinical Trials Administrative Office is responsible for conducting a Medicare coverage analysis for all clinical trials per UAB policy. This analysis provides an approved billing plan based on an objective determination of items/services that can and cannot be billed to third party payers using Medicare and local payer coverage rules along with clinical care billing guidelines. The CBR also evaluates any subsequent protocol amendments that modify the items/services required by the study and modifies the approved billing plan as needed. The approved billing plan is used to facilitate an accurate and appropriate clinical trial billing process.

- OnCore Enterprise is the University’s clinical trial management system (CTMS) designed for clinical research operations and data management at both the participant and study level. OnCore serves as the system of record for all clinical research studies with clinical billable services, serves as the source by which study and participant information flows to the health system’s electronic health record, and is managed and maintained by the UAB OnCore team. The team supports calendar building, reporting, education and training. For more information about OnCore, please visit the CTAO website https://www.uab.edu/medicine/ctao/investigators/oncore_enterprise

- PowerTrials integrates the clinical trial information into the workflow of the electronic health record to enhance both patient safety and appropriate billing practices for the University. Power Trials ensures availability of Research Study Summaries at the point of care to enhance patient safety and the development of PowerPlans to provide the foundation for appropriate billing practices.

The breakdown for the Study Management Fee is as follows:

- $4,500 covers all the costs above for “convened” reviews of industry-initiated and sponsored protocols by any outside IRB (such as WIRB) or “expedited review” by UAB IRB.

Revised January 25, 2019
Fees Charged by UAB for Industry-Initiated and Sponsored Protocols

- When WIRB or another outside IRB reviews a protocol, UAB charges a one-time fee of $4,500 for coordinating the initial review process and record keeping. Any fees charged by the outside IRB for their review is separate from the UAB fees described above.

- For expedited review conducted by the UAB IRB for industry-sponsored protocols, the UAB Study Management Fee is $4,500.

  - $5,500 covers all the costs above for "convened" review by UAB IRB of industry-initiated and sponsored protocols.
    - UAB charges a fee of $5,500 for providing convened review of protocols that are sponsored by industry but will not be reviewed by an outside IRB.

There is no UAB Study Management Fee for review of protocols that are UAB investigator-initiated or for studies funded by federal or nonprofit agencies.

Additional information is available as Frequently Asked Questions.
Fees Charged by UAB for Industry-Initiated and Sponsored Protocols

Frequently Asked Questions:
What fees applied to clinical trials prior to the Study Management Fee?
Prior to the effective date of the Study Management Fee, UAB charged the UAB Human Subjects Review Fee for industry-initiated and sponsored clinical trials. The Study Management Fee subsumes the UAB Human Subjects Review Fee previously charged for these trials.

When are the Study Management Fee and the annual Study Management Fee effective?
The Study Management Fee and the annual Study Management Fee applies to studies initially submitted to the UAB OIRB on or after February 11, 2019.

What trials are subject to the Study Management Fee?
All industry-initiated, industry-sponsored clinical trials are subject to the Study Management Fee. Click here for UAB’s definition of clinical trial. The Study Management Fee is due upon submission to the UAB OIRB regardless of whether or not the study receives IRB approval.

The Study Management Fee does not apply to UAB investigator-initiated studies or to studies that are funded by a UAB department or federal or nonprofit agencies.

My clinical trial doesn’t have clinical billables. When does this apply to this study?
All clinical trials will be managed through OnCore Enterprise by mid-2019 and all new clinical trials will be assessed this Study Management Fee. During the “phase in” period, studies without clinical billables will not be assessed the Study Management Fee. The previous UAB Human Subjects Review Fee of $2,000 or $3,000 will apply during this period.

How is the Study Management Fee allocated to the units that support clinical trials at UAB?
The allocation of the Study Management Fee is as follows:
• Office of the IRB (IRB) - $833 for outside IRB reviews and expedited reviews by the UAB IRB, and $1,833 for UAB IRB-reviewed protocols
• Office of the Conflict of Interest Review Board (OCIRB) - $333.
• Clinical Trials Administrative Office, including OnCore / PowerTrials - $3,334

This annual Study Maintenance fee supports the costs of the Clinical Trial Administrative Office, including CBR and OnCore / PowerTrials.

Do I have to pay F&A (indirect) costs on the Study Management Fees?
Yes. In compliance with the federal mandate under Uniform Guidance all sponsored projects are charged the appropriate F&A costs. The UAB F&A rates can be found here.

Who can I contact if I have questions about the Study Management Fee or the Study Maintenance Fee?
Contact Mark Marchant, Director of the Clinical Trials Administrative Office, at 205-934-2098 or marchant@uab.edu.
DATE: February 1, 2019
FROM: UAB Department of Medicine, Assistant Vice Chair for Research
RE: Summary of Departmental Fees associated with Clinical Research

The following Invoiceable Items need to be included in research projects conducted in the Department of Medicine at the University of Alabama at Birmingham. A description of the fees is included below. The fees outlined are minimum fees, the DOM leaves discretion to the individual research units to select the startup fee that applies to each project. A 30% IDC is included in the start up fees; please note that the fees could increase if a project requires a higher IDC rate based on UAB’s Office of Sponsored Programs requirements.

<table>
<thead>
<tr>
<th>Fee Description</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>START UP FEES (NONREFUNDABLE) Includes 30% IDC</strong> (Includes 30% IDC)</td>
<td></td>
</tr>
<tr>
<td>Administrative Start Up (Varies depending on complexity of the trial)</td>
<td></td>
</tr>
<tr>
<td>Simple ($6000-$12,000)</td>
<td>$6,000.00 - $22,000</td>
</tr>
<tr>
<td>Mid-level ($12,000-$22,000)</td>
<td></td>
</tr>
<tr>
<td>Complex (&gt; $22,000)</td>
<td></td>
</tr>
<tr>
<td>IDS Pharmacy Start Up</td>
<td>$2,500.00</td>
</tr>
<tr>
<td>Study Management Fee (<a href="https://www.uab.edu/research/administration/offices/OSP/Guidance/Pages/Study-Management-Fee.aspx">https://www.uab.edu/research/administration/offices/OSP/Guidance/Pages/Study-Management-Fee.aspx</a>)</td>
<td>$5850.00 / $7150.00</td>
</tr>
<tr>
<td>All WIRB Fees should be paid directly by the sponsor. If UAB is required to pay via pass-through, a 30-36% IDC will be assessed in addition to the WIRB fee.</td>
<td>Per WIRB Fee Schedule</td>
</tr>
<tr>
<td>IDS Pharmacy Start Up</td>
<td>$2,500.00</td>
</tr>
<tr>
<td>Radiology (one time)</td>
<td>$700.00</td>
</tr>
<tr>
<td><strong>ANNUAL FEES</strong></td>
<td>(Need to add IDC)</td>
</tr>
<tr>
<td>Study Management Fee</td>
<td>$1000.00</td>
</tr>
<tr>
<td>Regulatory</td>
<td>$1,100.00</td>
</tr>
<tr>
<td>Administrative Maintenance</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Pharmacy Annual Maintenance Fee (per year)</td>
<td>$520.00</td>
</tr>
<tr>
<td>Pharmacy Annual Storage Fee (per year)</td>
<td>$1,092.00</td>
</tr>
<tr>
<td><strong>STUDY FEES</strong></td>
<td>(Need to add IDC)</td>
</tr>
<tr>
<td>Continuing IRB Review Preparation and Submission Fee (per occurrence)</td>
<td>$630.00</td>
</tr>
<tr>
<td>Change of Protocol/ Change of Research Fee (per occurrence)</td>
<td>$630.00</td>
</tr>
<tr>
<td>Informed Consent Form (ICF) Change Fee (per occurrence)</td>
<td>$350.00</td>
</tr>
<tr>
<td>Service Description</td>
<td>Fee</td>
</tr>
<tr>
<td>--------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Contract Amendment (with budget modification) (per occurrence)</td>
<td>$1,600.00</td>
</tr>
<tr>
<td>Contract Amendment (without budget modification) (per occurrence)</td>
<td>$450.00</td>
</tr>
<tr>
<td>Consent Translation</td>
<td>$400.00</td>
</tr>
<tr>
<td>IND/IDE Preparation</td>
<td>$2,000.00</td>
</tr>
<tr>
<td><strong>CLOSE OUT FEES</strong></td>
<td><strong>(Need to add IDC)</strong></td>
</tr>
<tr>
<td>Archive Storage Fee (one time)</td>
<td>$1,300.00</td>
</tr>
<tr>
<td>Close Out Fee PI/Coordinator Time (one time)</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Close Out Fee Regulatory (one time)</td>
<td>$400.00</td>
</tr>
<tr>
<td>Pharmacy (one time)</td>
<td>$200.00</td>
</tr>
<tr>
<td>Post-Closure Data Retrieval</td>
<td>$350.00</td>
</tr>
<tr>
<td><strong>ADDITIONAL INVOICEABLE FEES (as applicable)</strong></td>
<td><strong>(Need to add IDC)</strong></td>
</tr>
<tr>
<td>CRO Fee (if applicable)</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Re-consenting Fee (per occurrence)</td>
<td>$150.00</td>
</tr>
<tr>
<td>Change in Study Database</td>
<td>$600.00</td>
</tr>
<tr>
<td>Monitoring Fees</td>
<td></td>
</tr>
<tr>
<td>Change in Monitor Fee (per occurrence)</td>
<td>$400.00</td>
</tr>
<tr>
<td>Re-monitoring Fee (per occurrence)</td>
<td>$250.00</td>
</tr>
<tr>
<td>Multiple Monitors Fee (per additional monitor)</td>
<td>$150.00</td>
</tr>
<tr>
<td>Additional Sponsor Visits Fee (per day)</td>
<td>$150.00</td>
</tr>
<tr>
<td>Remote Monitoring Fee (per occurrence)</td>
<td>$500.00</td>
</tr>
<tr>
<td>SAE Reporting (per report)</td>
<td>$250.00</td>
</tr>
<tr>
<td>IND Safety Letters (per report)</td>
<td>$25.00</td>
</tr>
<tr>
<td>Sponsor Required Additional Training (Coordinator) (per hour)</td>
<td>$75.00</td>
</tr>
<tr>
<td>Sponsor Required Additional Training (Investigator) (per hour)</td>
<td>$275.00</td>
</tr>
<tr>
<td>Teleconferences (per occurrence, per hour, per attendee)</td>
<td>$75.00</td>
</tr>
<tr>
<td>Sponsor and/or FDA Audit Fee (per occurrence)</td>
<td>$2,300.00</td>
</tr>
<tr>
<td>Travel Reimbursements (per submitted receipts, plus the applicable IDC rate)</td>
<td>Variable</td>
</tr>
<tr>
<td>Additional Pharmacy Fees (varies by study)</td>
<td>Per pharmacy fee schedule</td>
</tr>
</tbody>
</table>
START-UP FEES

ADMINISTRATIVE START-UP FEE
The Administrative Start-Up Fee covers the managers and other research staff time that is neither patient, nor IRB specific. This may include:

Site Qualification Activities:
- Routing confidentiality agreements
- Completing site questionnaires
- Use of i2B2 for feasibility data
- Feasibility assessment, including in-depth review of protocol
- Scheduling and conducting Site Qualification Visit, providing facilities tour, etc.

Required Protocol Reviews - Includes preparation/submission/securing approval of the following institutional committees:
- Scientific Review Committee – The Scientific Review Committee performs scientific review of all research conducted at the UAB site.
- Coverage Analysis Committee Review – The site prepares a billing matrix that is then reviewed and approved based on an objective determination of items/services that can and cannot be billed to third party payers using Medicare and local payer coverage rules along with clinical care billing guidelines.

Preparation for Study Conduct, including:
- Create protocol-specific physicians order sets; coordinate protocol review and input from pharmacy, nursing, laboratory.
- Create Fast Facts Sheet to provide study information to UAB referral office and non-UAB referring physicians.
- Create study-specific tools including calendars, data collection forms, appointment slips, CRU flow sheets, insurance pre-approval requests, etc.
- Coordinate staff training sessions prior to study activation with nursing, Research Pharmacy, Laboratory, Radiology Research and others, as needed.
- Complete sponsor-required training modules. It is assumed that each study will have a minimal amount of study-specific training associated with it (up to one hour of training for PIs, and up to 2 hours of training for study coordinators). For studies with extensive training requirements an additional hourly fee may apply.
- Complete UAB database entry for regulatory submissions, subject enrollment and financial tracking.
- Prepare and distribute copies of protocol, consent forms and investigational brochure to participating clinic staff, inpatient unit(s), and study coordinator reference binders.
- Prepare and submit to sponsor all regulatory documents including Financial Disclosures, CVs, FDA Form 1572, Laboratory Certifications and Reference Ranges, Staff Signature Logs, Medical Licenses, and other required items.
- Schedule and conduct Site Initiation Visit (SIV).
- ICH-GCP training/certification

IRB Initial Submission:
- Modify sponsor’s informed consent template for inclusion of UAB-specific language
• Prepare and submit initial IRB submission and any applicable additional items needing to be reviewed

Fiscal Activities:
• Budget preparation: Review protocol and request budgetary input from pharmacy, radiology, clinical team, laboratory, and other ancillary departments as required; determine research personnel time; enter all study-specific costs into the UAB CTMS to generate patient care costs; prepare completed budget for submission to sponsor; and negotiate budget with sponsor and involved entities.
• Contract/budget routing: Prepare finalized Clinical Trial Agreement (CTA) documents and coordinate multi-level review within the UAB system.
• Hospital Letter of Agreement (LOA)/Purchase Agreement routing for device trials: Prepare LOA documents and coordinate multi-level review within the UAB system.
• Establish fund account; set up internal/external billing mechanisms for pharmacy, hospital costs, and other services; verify compliance billing mechanism is in place for use by the study team.
• Complete any sponsor required training related to fiscal management of study

STUDY MANAGEMENT FEE
The Study Management Fee addresses costs associated with reviews and work conducted on industry-initiated and sponsored protocols by several areas involved in the activation process, which includes the following:

• The Office of the IRB (IRB) performs a pre-review of the protocol for institutional and WIRB requirements and stores, maintains, and updates the file through the life of the protocol at UAB. If applicable, the UAB IRB will conduct an expedited or full review.
• The Office of the Conflict of Interest Review Board (OCIRB) must review the responsible personnel on the project and their associated financial interests to ensure any conflicts that may exist are managed appropriately. These reviews occur as needed throughout the life of the protocol at UAB.
• The Clinical Billing Review (CBR) unit of the Clinical Trials Administrative Office is responsible for conducting a Medicare coverage analysis for all clinical trials per UAB policy. This analysis provides an approved billing plan based on an objective determination of items/services that can and cannot be billed to third party payers using Medicare and local payer coverage rules along with clinical care billing guidelines. The CBR also evaluates any subsequent protocol amendments that modify the items/services required by the study and modifies the approved billing plan as needed. The approved billing plan is used to facilitate an accurate and appropriate clinical trial billing process.
• OnCore Enterprise is the University’s clinical trial management system (CTMS) designed for clinical research operations and data management at both the participant and study level. OnCore serves as the system of record for all clinical research studies with clinical billable services, serves as the source by which study and participant information flows to the health system’s electronic health record, and is managed and maintained by the UAB OnCore team. The team supports calendar building, reporting, education and training. For more information about OnCore, please visit the CTAO website.
**PowerTrials** integrates the clinical trial information into the workflow of the electronic health record to enhance both patient safety and appropriate billing practices for the University. Power Trials ensures availability of Research Study Summaries at the point of care to enhance patient safety and the development of PowerPlans to provide the foundation for appropriate billing practices.

The breakdown for the *Study Management Fee* is as follows:

- **$4,500 covers all the costs above for “convened” reviews of industry-initiated and sponsored protocols by any outside IRB (such as WIRB) or “expedited review” by UAB IRB.**
  - When WIRB or another outside IRB reviews a protocol, UAB charges a onetime fee of $4,500 for coordinating the initial review process and record keeping. Any fees charged by the outside IRB for their review is separate from the UAB fees described above.
  - For expedited review conducted by the UAB IRB for industry-sponsored protocols, the UAB Study Management Fee is $4,500.
- **$5,500 covers all the costs above for “convened” review by UAB IRB of industry-initiated and sponsored protocols.**
  - UAB charges a fee of $5,500 for providing convened review of protocols that are sponsored by industry but will not be reviewed by an outside IRB.

There is no UAB Study Management Fee for review of protocols that are UAB investigator-initiated or for studies funded by federal or nonprofit agencies. [https://www.uab.edu/research/administration/offices/OSP/Guidance/Pages/Study-Management-Fee.aspx](https://www.uab.edu/research/administration/offices/OSP/Guidance/Pages/Study-Management-Fee.aspx)

**INVESTIGATIONAL DRUG SERVICE (IDS) PHARMACY FEES**

The UAB Research Pharmacy is responsible for the proper storage and distribution of investigational drugs for all research patients. Commercially available drugs may be considered investigational if the drug is obtained by the investigator outside of the normal hospital purchasing process.

The investigational drug pharmacist assists investigators in planning and executing clinical trials using investigational drugs. The pharmacist also assists in the randomization and “blinding” process.

- Appointments are required for tours and audits.
- They provide limited access, locked ambient refrigerator and freezer storage for Investigational drugs within the Central, Storeroom, and Research Pharmacy areas of North Pavilion.
- They utilize the appropriate workspaces within the Central Pharmacy 797 clean room for the preparation of injectable doses.
- The Alabama State Board of Pharmacy laws are followed regarding: space, storage and labeling.
- Ambient temperature is thermostatically controlled to allow for a temperature range of 68F (20C) to 77F (25C). If noted that the ambient temperature is out of the allowed
range, the maintenance department will be contacted immediately to determine and correct the problem. If the temperature exceeds 86F (30C), documentation will be provided in drug accountability records. Study sponsors will be contacted if necessary. Limited space is available for storing drugs at 2-8 C, -20 C, and -80 C. Within range documentation is provided daily. UAB Central Plant & Utilities electronically monitors these units, refrigerators and freezers are on emergency power circuits and UAB Hospital Maintenance is available 24 hours day to respond to problems. A pharmacist is paged if the unit temperature is “out of range”. Study sponsors will be notified if necessary.

**IDS Pharmacy Start-up Fee:**
This fee is assessed to compensate for the Pharmacy staff time dedicated to:
- Review of protocols and investigational brochures
- Participation in Sponsor visits: Pre-site visit, Start-up, Close out
- Study setup in the Web IDS system
- Establish drug procurement, shipment receipt and distribution procedures
- Create drug accountability record

**Annual Storage Fee:**
- Assure proper storage conditions for investigational products

**Annual Maintenance Fee:**
- Review changes to protocol and/ or investigational brochure
- Prepare for and participate in sponsor monitoring visits.
- Maintain Web IDS, an electronic database for:
  - Protocol information
  - Inventory management
  - Dispensing functions
- Provide protocol specific information and education as needed for pharmacy staff
- Post information as needed on the Pharmacy Department Intra-net.
- Perform randomization activities
- Monthly billing for services provided

**Pharmacy Preparation and/or Dispensing Fees**
These fees are captured in per-subject cost: This fee covers the cost to prepare the study medication(s) for administration and the corresponding drug accountability documentation. The fee covers data entry into the pharmacy’s computerized medication administration or outpatient profile record and the time involved with labeling, counting, repackaging (if applicable) or sterile compounding under aseptic and biohazardous (if applicable) conditions and drug accountability entries.

**STUDY FEES**

**CONTINUING REVIEW- IRB SUBMISSION AND PREPARATION FEE**
A fee is assessed for each IRB continuing review to compensate for the Regulatory staff time dedicated to preparing and submitting the required documents to the IRB. Depending on the complexity of the study, this could occur quarterly, bi-annually, or annually.

**CHANGE OF PROTOCOL/ CHANGE OF RESEARCH FEE**

A fee is assessed for each Change of Research to compensate for the staff time involved in:

- Reviewing the change to determine its impact on the current study conduct, preparing and submitting the required documents to the IRB
- Reviewing and processing IRB approval documents
- Distributing revised protocol, consents, or other study documents
- Training Investigators and staff on the new information contained in the amendment.

**INFORMED CONSENT FEE (ICF) CHANGE FEE- IRB SUBMISSION AND PREPARATION FEE**

A fee is assessed for each ICF change required by the sponsor. This fee is to compensate for the Regulatory staff time dedicated to preparing and submitting the required documents to the IRB, reviewing and processing the IRB approved documents, and distributing the revised ICF.

**ARCHIVING/STORAGE FEE**

Archiving/storage fees apply to the time dedicated on the part of the site staff to maintain study records according to FDA Guidelines and/or the Clinical Trial Agreement, including preparation for storage, tracking of record locations and retrieval of records for sponsor visits.

**CLOSEOUT FEE**

A fee is assessed for the closeout activities of each trial to compensate for the staff time dedicated to:

- Final financial reconciliation of hospital bills, ancillary department bills, account review and closure, preparation of final invoice to sponsor, processing final sponsor payments, etc.
- Disseminating sponsor closeout correspondences to research staff members.
- Preparing for and participating in close out visit.
- Preparing and submitting closure documents to the IRB of record.

**IRB FEES**

The UAB IRB is composed of members from various disciplines in the medical, social, and behavioral sciences, as well as community members. The UAB IRB is committed to protecting the rights and welfare of individuals participating in research at UAB.

In addition, the UAB IRB has contracted with a well-known and widely used commercial IRB, the Western IRB (WIRB), for the review of industry-sponsored research studies. WIRB fees vary and are payable directly to WIRB. The WIRB fee schedule may be obtained from WIRB Client Services at 1-800-562-4789 or clientservices@wirb.com. These rates are based on the current WIRB fee schedule and are subject to change. If a sponsor is not contracted with WIRB and requests that the site pay WIRB directly, the sponsor will be invoiced for paid WIRB charges and the applicable overhead for the study will also be assessed.

All IRB fees will be invoiced separately by the respective IRB and should be paid directly to the IRB. These fees are not considered a part of the contract budget.
ADDITIONAL INVOICEABLE FEES

CRO FEE
The CRO fee is assessed when the site is required to work through a Clinical Research Organization instead of directly with the sponsor.

RE-CONSENTING FEE
A fee is assessed for each subject re-consented to compensate for the time dedicated on the part of the research team to re-consent the subject.

CHANGE IN STUDY DATABASE
This fee is assessed to compensate for staff dedicated time to re-enter data that has already been entered in a previous database. If the sponsor enters the data; this fee will not be charged.

MONITORING FEES

Change in Monitor Fee:
This fee recognizes that additional time is required by the research team when a sponsor monitor is replaced during the course of the study. New monitors require orientation to the UAB site, review of UAB site monitoring guidelines and procedures, and the organization of study records.

In addition, new monitors will often re-review previously monitored data, requiring additional time from the research team to answer questions and potentially repeatedly revise data. We recognize that it is not unusual for sponsors to have a ‘start up’ team that is distinct from the ongoing monitoring team, and for this reason the Change in Monitor Fee applies beginning with the third monitor to join the study.

Re-Monitoring Fee:
A fee is assessed on a per visit basis to compensate research staff time involved in additional monitoring. This includes, but is not limited to:
- Monitor reviews same data again.
- Monitor arrives to site unprepared and/or untrained and requires a rescheduled visit.
- Collection of data after monitoring visit that was available during monitoring visit.

Multiple Monitors Fee:
A fee is assessed to compensate for additional research staff time dedicated to working with multiple monitors during a monitoring visit. This increases the demand on staff time to respond to multiple monitors regarding the same trial. The fee will be assessed on a per visit basis.

Additional Monitor Visits Fee:
A per visit day fee is assessed for sponsor required visits beyond our standard guidelines. Our standard study related visits are as follows:
- Close out visits equals 1 day
- SIV equals 1 day
- Monitoring visits equals 1-2 days
- Monitoring visits every six to eight weeks

Remote Monitoring Fee:
If a sponsor will not be coming on site to monitor the study data, but instead requires study data to be monitored remotely, a fee will be assessed for the additional staff time and effort that is required in a remote monitoring scenario.

SAE REPORTING
In order to offset personnel costs incurred by SAE reporting, a fee may be assessed for each SAE reported for UAB enrolled patients. This fee will cover personnel effort for reporting SAEs both internally and externally as required by the sponsor and the IRB of record.

IND (OUTSIDE) SAFETY REPORTS (INDSR) FEE
This fee reimburses the site staff time dedicated to processing each INDSR received. This process may include the following:
- Review of INDSR to determine causality to study procedure or agent and whether the report meets further review by the IRB of record
- Process INDSR where sponsor requires additional steps to confirm receipt (e.g., fax return or retrieval from web based system).

SPONSOR REQUIRED ADDITIONAL TRAINING
A fee is assessed for additional training required by the sponsor to compensate for staff dedicated training time. This hourly fee will be charged for each staff member requiring additional training after study activation.

TELECONFERENCES
A fee is assessed for participating in teleconferences to compensate for staff time dedicated to the call.

SPONSOR AND/OR FDA AUDIT FEE
While the site operates in such a manner as to always remain sponsor and/or FDA audit “ready,” we also realize that when these type audits occur, additional time is required of the research team. Our FDA audit Standard Operating Procedure requires that the FDA auditor be monitored by a site staff member at all times. Requiring this means that the research team is unable to devote their time to any of their other studies or duties during the audit. This fee covers this lost time to participate in other study activities and duties during the audit.

TRAVEL REIMBURSEMENTS
Many of our eligible UAB patients live over 50 miles away. Hotels stays might be required to assure our patients are able to maintain their protocol visit schedules. With sponsor prior approval, the site staff will make the hotel reservation and invoice the sponsor accordingly. Mileage is reimbursed at the current federal standard mileage rate.