

Clinical Trialist Development Program (CTDP)

Background: Over the past ten years, industry-sponsored clinical trial expenditures at the University of Alabama at Birmingham (UAB) have shown steady growth. Sustaining and/or accelerating this momentum depends on expanding the pool of clinician-investigators who have the motivation, training, and support needed to serve as principal investigators (PIs) on industry-sponsored clinical trials. Several barriers hinder clinician-investigators from taking on PI roles. These include inadequate training on how to lead clinical trials, insufficient resources to conduct trials, and a lack of salary support to allow dedicated time for developing a portfolio of clinical trials. To address these issues, dedicated support at the University level is needed to expand the pool of clinician-scientists with a career focus and expertise in clinical trials, particularly industry funded trials.

Goal: The Clinical Trialist Development Program (CTDP) will identify and support promising faculty with an interest in developing or expanding clinical trial expertise. Through the provision of protected time and mentoring, the faculty members selected for the CTDP will develop clinical trial portfolios that will contribute to an increase at UAB in industry-sponsored clinical trials.

Proposal: State-appropriated funds for the UAB Clinical Trial Initiative will support clinical faculty with substantial interest and potential in serving as PIs on industry-sponsored clinical trials. Successful candidates will be identified through a competitive application process. To be eligible, an applicant must meet the following criteria:

- UAB faculty member at the rank of Assistant Professor or Associate Professor
- Prior or current participation in at least 1 industry sponsored clinical trial as PI, site PI, or sub-investigator

Faculty who meet these criteria may submit an application for the CTDP that will include the following elements:

- Statement of research interest in clinical trials, and plan to develop or expand expertise as a clinical trialist (2 page maximum)
- Documentation of prior involvement in clinical research (number of trials served as PI, site PI, sub-investigator, etc.)
- Letter of support from Division Director, Department Chair, and/or Dean's Office, including a commitment to protect at least 20% of total time (UAB +HSF) to serve as PI on clinical trials
- Letter of support from her/his identified mentor (senior clinical trialist) at UAB

All applications will be reviewed and scored by a Review Committee comprised of senior clinical trialist faculty members. Each School and College in which clinical trials are conducted will have its own Review Committee. Applicants who receive support from their School/College committee will be advanced to the Selection Committee that will be appointed by the UAB President. Final determination of inclusion in the CTDP resides with the Selection Committee.

Applicants chosen by the Selection Committee for participation in this two-year program will receive the following:

- Support to participate in the Clinical Investigator Training Program (CITP) within the first year (mandatory), unless the applicant has already completed this or a comparable clinical trial training program.
- Two years of protected time of at least 20% of total effort (UAB + HSF) to provide dedicated time towards developing her/his clinical trials portfolio. This protected time will be allocated by the Division/Department/School.
 - o During Year 1 of the successful applicant's involvement in the program, the CTDP will provide salary support of up to 20% of the NIH cap, inclusive of both salary and fringe.
 - o During Year 2 of the the successful applicant's involvement in the program, the Department or School will provide salary support adequate to protect at least 20% of total effort (UAB + HSF).
- Selected applicants can also apply for a "voucher" from the CTDP that can be used to receive services from the UAB Clinical Research Support Enterprise (CRSt) to assist the CTDP participant with key start-up, budgeting, or study management activities. To encourage the identification and engagements of mentors, selected applicants may also use these vouchers to support the mentor's research program by accessing CRSt services or by supporting existing comparable expertise within their research unit.

- Time-to-Activation of projects conducted by CTDTP participants will be actively overseen by Dr. David Kimberlin and the faculty member's school to ensure prompt study initiation.
- Quarterly group meetings with Dr. Dana Rizk and Dr. David Kimberlin will be held with all CTDTP participants to create a near-peer community, share best practices, and identify and overcome barriers to success.
- Identified mentors will submit bi-annual short progress reports highlighting the applicant's achievements.

Key metrics of success for the program will include:

- Increasing number of UAB clinical trialists
- Number of industry-sponsored clinical trials (per NIH definition) on which the CTDTP participant serves on as site PI
- Annual target enrollment achieved in the clinical trials for which the CTDTP participant serves as site PI (goal of $\geq 85\%$ enrollment)
- Expenditures from trials led by CTDTP participants as site PI
- Retention of CTDTP participants as clinical trialists at UAB (over 3-5 year horizon)