UAB CLINICAL TRIALS ADMINISTRATION COMMITTEE

CHARTER

ROLE:

The Clinical Trials Administration Committee promotes continuous improvement toward excellence in clinical trials administration throughout UAB. To this end, the Clinical Trials Administration Committee guides the Clinical Trials Administrative Office and supports the President's Risk Cabinet by establishing requirements and monitoring processes to enhance effectiveness and financial sustainability in clinical trials administration in all units within the University. Examples include:

- · Customer satisfaction;
- Patient and subject safety;
- Strategic areas of excellence;
- Financial feasibility and sustainability;
- Process efficiency;
- Legal and regulatory compliance; and
- Timely and accurate billing for standard of care and study charges.

MEMBERSHIP:

The Chair of the Committee will be appointed by the UAB Vice President for Research and Senior Vice President/Dean of the School of Medicine, in consultation with the Senior Vice President/Provost and UAB Health System CEO. The Clinical Trials Administration Committee is comprised of faculty representatives from each school performing clinical trials, University and UAB Health System administrators or representatives in positions suited to provide broad perspective on risks and opportunities associated with clinical trial activities, operations, strategies and financial performance. The Committee Chair will recommend a selection of committee members to the designated executive leadership for approval. Additionally, sub-committees may be formed to lead the development and implementation of policies and procedures that govern those specific areas of responsibility. In these instances, sub-committee membership may not be limited only to members of the Clinical Trials Administration Committee.

MEETINGS:

The Clinical Trials Administration Committee meets monthly, individual sub-committees meet on an as needed basis.

RESPONSIBILITIES:

Responsibilities of the Clinical Trials Administration Committee include, but are not limited to, the following:

 Promote an organizational culture that integrates clinical trials administration consistent with institutional objectives into the daily activities of University employees;

- Provide advice and guidance to the Clinical Trials Administrative Office on the enhancement of
 clinical trials administration on topics including but not limited to training and education of
 principal investigators and study teams, adherence to legal and regulatory requirements,
 information technology and data systems, responsible financial management, and study
 participant safety and incentives;
- Develop, review, authorize, and implement policies and procedures of the Clinical Trials Administration Manual, assuring overarching policymaking goals of quality, transparency, efficiency, financial sustainability and broad input from relevant stakeholders are met;
- Review assessments of risks, mitigation or corrective action plans, and implementation results;
- Coordinate efforts and initiatives of the Clinical Trials Administrative Office with other research
 administration offices, such as Office of Sponsored Programs, IRB, etc., to avoid duplication, as
 well as to allow for the sharing of resources and information; and
- Report progress on effectiveness of clinical trials administration, including financial performance, to the President's Risk Cabinet on an annual basis.

ADOPTED AND APPROVED BY PRESIDENT'S RISK CABINET ON FEBRUARY 20, 2018.

Ray L. Watts, President

Date

2/22/18