ADMINISTRATIVE POLICY

Covering Start Up Costs for Clinical Trials Policy

Policy Type: Finance
Policy Owner(s): Finance Manager
Policy contacts: Andrea Johnson
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POLICY STATEMENT

In order to fast track the trial set-up process, TRUC approved trials do not require that funding be secured prior to building a clinical trial budget. Work is started immediately by

- Project Managers
- Regulatory Staff

Process

Staff log hours in the portal, invoices are generated and sit in a pending status.

Start-up costs are negotiated as a part of the contract for B & I funded trials. Budgets are built for Investigator-initiated trials upon request. When a contract is signed for a B & I sponsored trial or funding secured for an Investigator-initiated trial, time logged as a part of the trial set up is charged. If a sponsor does not agree to the contract, every attempt is made to secure start-up funding sufficient to cover costs already incurred and the trial is abandoned. If funding was secured, it is applied to pending invoices. If no funding can be secured, MCC will pay the pending invoices.

Under no circumstances is a trial opened to accrual without funding being identified and a corresponding EFS string entered into the portal.