At-Risk Accounts for Industry Sponsored Clinical Trial Agreements

Along with three academic departments, OSP, the IRAP support team, and GCA have been piloting a pending account process for industry sponsored clinical trial agreements for the last several months. “At-Risk Accounts” (aka “Pending Accounts”) are used to assist in tracking the actual cost of conducting a clinical trial, therefore, it is very important that the clinical departments use the At-Risk Account to facilitate appropriate accounting for expenditures associated with study activation including, study start-up fees and personnel expenses.

Effective January 1, 2017, this process will be rolled out across campus.

What is the Process?

1. OSP receives your complete submission; including a signed Extramural Checklist for an Industry sponsored clinical trial.
2. The OSP Officer reviews the Extramural Checklist and updates IRAP, which triggers a notification to grants and contracts accounting.
3. Accounting sets up the At-Risk Account and notifies the PI/department. The start date of the pending/at risk account will be 1 year prior to the receipt date of the checklist by OSP to enable sites to charge activities related to study start up. And the account will remain ‘pending’ for 1 year after creation unless the account is either activated or terminated.

Department/Site applies start-up charges to the new account and then continues to use when becomes active. This includes start-up fees for IRB, Pharmacy, Radiology, etc., as well as personnel expenses associated with the time required for study activation procedures.