



GCAAlert!

Yale University

Grant and Contract Administration

Grant and Contract Financial Administration

Volume 3, Issue 1

Week of June 8 – June 12, 2009

Alerts:

- **New Process for Industry Sponsored Clinical Trial Account Setups**
- **Auto-Email Compliance Reminder Notifications**

“...the completion of form 1304 FR.01 Departmental Request (DR) for Opening an At-Risk Account is no longer required to activate a new industry sponsored clinical trial...”

“No award can be set up (including an “at-risk” account) and no expenses can be incurred related to the sponsored project until all applicable compliance requirements have been met.”

Grant & Contract Administration

47 College Street, Ste 203
203-785-4689

155 Whitney Avenue,
Room 214
203-432-2460

Grant & Contract Financial Administration

155 Whitney Avenue,
Room 230
203-432-3060

New Process for Setting up Industry Sponsored Clinical Trial Accounts

Current practice dictates that even with a fully executed agreement, completed ProSum, IDX form, project budget (if applicable) and verification of HIC/IRB protocol/congruency approval, industry sponsored clinical trials for which an initial payment has not yet been received must be set up “at risk”. Representatives from Grant and Contract Administration (GCA), the Award Setup Unit (ASU), Financial Operations, and the ORA Compliance Unit met recently and determined that the completion of form 1304 FR.01 Departmental Request (DR) for Opening an At-Risk

Account is no longer required to activate a new industry sponsored clinical trial account as long as the clinical trial is in full compliance and the following documentation is provided to GCA:

- Fully executed agreement
- Completed ProSum
- IDX Form
- Trial budget (if applicable)
- Verification of HIC/IRB protocol/congruency approval.

Please keep in mind, however, that departments are still responsible for any charges,

which are not covered by the sponsor. Therefore, it is very important for departments to let ASU know immediately (i.e. as soon as you get your award notices) of any awards you think should not be activated. ASU will then be able to put the account “on hold”. We believe the process will not be cumbersome because of the rare instances when a trial reaches full execution and then is cancelled or closed.

Please direct any questions concerning this change in procedures to your GCA Team representative or to gcacommunications@yale.edu.

Auto-Email Compliance Reminder Notifications

The Office of Grant and Contract Administration (GCA) has recently begun to send automated email notifications to Principal Investigators – upon proposal submission and 60-days prior to the proposed start date of an award – as reminders that no award can be set up (including an “at-risk” account) and expenses cannot be incurred related to the sponsored project until all applicable compliance requirements have been met.

Once GCA submits a proposal to a sponsor and the Principal Investigator (PI) is notified of imminent funding for that proposal, the PI must ensure that the following compliance requirements are fulfilled before a sponsored account can be established:

- **Conflict of Interest (COI):** All personnel responsible for the design, conduct, or reporting of this research must be listed in Section

VII of the Proposal Summary and Certification Form (ProSum). The PI is responsible for notifying GCA immediately if there are any changes to this list at any time. All Section VII personnel (including the PI) must have a current COI Disclosure on file with the COI Office.

- **Institutional Review Board (IRB) Review and Approval:** If the proposal involves the use of human subjects, the research must have IRB approval from the Human Investigation Committee (HIC), Human Research Review Committee (HRRC), or the Human Subjects Committee (HSC). The IRB is required to confirm that the research described in the proposal to the sponsor is consistent with the research described in the IRB approved protocol – this is referred to as

“protocol-proposal congruency”. IRB approval and congruency must be verified before an award will be setup.

- **Institutional Animal Care and Use Committee (IACUC) Review and Approval:** If the research involves the use of animals, the research must have IACUC approval. In addition to protocol approval, the IACUC is required to confirm that the research described in the proposal for funding is consistent with the research described in the IACUC approved protocol – this is known as “protocol-proposal congruency”.

Please review the ORA Newsletter article located at <http://www.yale.edu/oranewsletter/archive4/feature2.html> for further information regarding protocol-proposal congruency determination.