

OPPORTUNITIES FOR IMPROVEMENTS:

1. Contracts/Grants

Per confirmation with Lorraine Twerdok, contractual/grants agreements exist between API on behalf of the BHRC consortium and the various studies/items listed above with the exception of Fudan University – Epidemiology Case Control Study and QA/QC Support. Outside Legal Counsel costs are contracted separately through API and charged back to the study. Although there was not enough time to review individual contracts, an overview of project activities, estimated costs, contract time period, milestones, and other associated activities should be stated in each contract. API and BHRC Committee should consider reviewing all contracts and obtaining contracts for Fudan University and QA/QC Support.

Recommendations

It is recommended that API work with the BHRC Oversight/Technical Committee, to review and or rewrite (if necessary) the contracts to include and/or exclude addendums, attachments, letters, etc. related to the above mentioned study activities. In addition, contracts should be obtained for Fudan University and QA/QC support.

To further assist in obtaining confidence and controls that the approved budgeted project will not exceed \$22,789,300, the committee may want to consider obtaining a letter/agreement from API stating such and list the possible activities and costs that may exceed the current approved budget.

It is further recommended that a letter or contractual alterations document any and all future changes.

Action Required By: API and BHRC Committee

2. University of Colorado (UCHSC)

The University of Colorado (UCHSC) study operates under a grant which encompasses the DP and ME studies which totals \$15,258,000. This represents approximately 67% of total project costs. As of December 2002, API has paid on behalf of the consortium \$7,515,759, as agreed, with another scheduled payment of \$5,040,261 due August 2003. As of March 2003, API reports UOC has spent \$4,136,955 leaving UOC with a balance of \$3,378,795.

Recommendations

Although grants are regarded differently, API and BHRC committee should consider addressing the following questions:

- Will projected funds be used?
- Should payment schedule be revised so that UOC is not holding large cash balances?
- Is interest collected on excess funds and are they

contributed back to the study as to supplement costs?

- Is UOC able to provide specific documentation, such as invoices, etc. if needed?
- Who audits the UOC financial tracking of study?

Action Required By: API and BHRC Committee

3. University
of Colorado
(UCHSC)

Progress reports are sent to API twice a year. Costs for a separate Fudan University project, Richard Irons project and EMBSI costs are currently included and tracked by UOC. API mirrors the data reported by UOC and has no means of validating actual expenses to make sure the consortium is not charged twice.

Recommendations

It is recommended that API, as project administrator, validate the expenses incurred as reported from UOC's progress reports via an audit proposed by the consortium. To avoid possible duplication of costs, validation is required to make sure the same type of cost included in UOC's project is not the same as the projects costs tracked individually by API.

Action Required By: API and BHRC Committee

4. Financial Tracking

Currently API uses a contract management tool to track costs associated with the study, which is updated by the financial department at API. Once updated, Paula Podasky receives the data from finance and uses the data to report costs that go against the contracts for reporting actual expenses incurred for all studies except for UCHSC (explained above). Currently there are various formats and time periods used to report various financial study data and project financial summaries. Currently it is difficult to get a financial picture at any given time. Actual as well as budgeted data constantly changes. This information should be tracked monthly or quarterly to maintain stability. A financial tracking tool or format is necessary that can easily be updated by a finance person. Note: During the review there was not an opportunity to address who reviews/approve expenses associated with the study under API's responsibilities.

Recommendations

It is recommended BHRC committee set a specified time frame for periodic updates (monthly, quarterly, etc.) and an agreed upon format for each Benzene Study item which will present a financial picture at any specified time.

(See attached file entitled "Benzene-API Executive Summary" Exhibit A for suggested Executive Summary format for overall project and file "Benzene-API – Applied Health Study" - Exhibit B is a suggested format for reporting individual project items – example is for Applied Health Sciences Study.)

Recommendations

It is further recommended, if necessary, an additional process audit review to interview API finance department to understand processing of expenses under API's responsibilities. This includes

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all except UCHSC. There does not seem to be an easy way to get drill down information on any of expenses paid. Backup of expenses paid on the project should be easily identifiable as to what was spent on the project.

Action Required By: API and BHRC Committee

5. Budget Revisions

Various budget changes have occurred since the beginning of project in 2001, with the most recent changes documented via e-mail dated June 19, 2003 from Lorraine Twerdok to the BHRC Oversight and Technical Committees. Some committee members were not aware of the changes. For example Fudan University cost went from \$190,555 to \$661,000. Although the overall budget did not change, there was no approval process by the committee to accept changes. API received a one-page summary of figures with no clear explanations for increases from Fudan.

It is recommended a mechanism for documenting changes be implemented immediately that has the approval of the committee in writing to API before budget changes are made.

Action Required By: API and BHRC Committee

6. Documentation
/Backup

Record keeping at API is based largely on manual data received. API should have a contingency plan in place to back up manual and system data in cases of emergency.

It is recommended API review and validate data backup process.

Action Required By: API

Should you have any questions regarding the audit, please contact me at (713) 241-6682.

Very truly yours,
Tarita Samuel

cc: BHRC Oversight and Technical Committees