
Research Support Services Task Force

EXECUTIVE SUMMARY

(draft 6-5-97)

In September 1996, Academic Health Center Frank Cerra created the Research Support Service Task Force to examine the process of applying for, receiving, and reporting on industry-sponsored research. The objectives were to enhance the ability of faculty to market their research capabilities and improving compliance with government regulations.

The task force found

- there are no time performance demands placed on any area, committee or office involved in overall internal processes of grant submission and approval.
- there is much "down" time, when a grant or contract just "sits" in an office or committee.
- there is little regard for how the efforts of each office or committee might make the process more user friendly for faculty and sponsors.
- there has been little attention to "parallel processing", where multiple internal approvals could be completed simultaneously--thereby reducing the time it takes to complete a review.

More specific task force findings dealt with 1) the Conflict Review Committee, 2) principal investigator responsibility, 3) subjects protection programs-human subjects, 4) ORTTA patents and technology marketing, 5) ORTTA sponsored research programs, 6) coordination of clinical trials review processes, 7) the General Clinical Research Center, 8) monitoring compliance with research regulations.

One of the critical observations made by the task force is a pervasive lack of performance criteria for almost every component of a research contract, including submission, approval and execution of the research. Task force members were struck by that fact that there is little or no regard for the value of time.

Overall, the task force recommended the following actions:

- Establish very rigorous performance criteria for each office, unit, or committee that is involved in initiation, approval, performance, and closing of research projects sponsored by outside corporations. Assume that professionals in these offices have the authority they need and hold them accountable. There is a need to adopt more of a service mentality on the part of the staff.
- Establish a parallel review and approval process for all internal approvals. In negotiations, no 24-hour period should expire without the appropriate university official contacting both the corporation's representative and the university faculty member. It is the expressed goal of the task force to have the internal process completed in 10 working days without sacrificing the current highly quality of the review.
- Establish a process in which an activity sheet will be placed on the front of each contract or grant that tracks time in and time out with a uniform office stamp.
Professionals in the office would initial the grant as it moves along. This would establish a log of all actions and time taken to accomplish the work. Once this became routine, it would not be intrusive.

The task force also offered specific recommendations to address the issues that emerged from the principal findings:

- Disband the Conflict Review Committee and establish a new AHC committee, the Conflict Review and Management Committee, to review conflict of interest issues.
- Establish a Research Support Services Office and director reporting to the provost to provide research support to investigators seeking assistance with industry-sponsored research.
- Establish a Business Development Office within the RSSO to identify technology and services that could be protected by licensing, patents, or trademarks, to advise faculty about intellectual property, to market faculty research and services, and to establish a Technology Research Pool to invest in promising projects.
- Enhance performance of subjects protection programs--human subjects review process to provide sufficient staff to train, consult and provide information services to the research community on an on-going basis, to use video-conferencing, e-mail, courier and fax services to improve the IRB review process, and to establish a web site to post IRB results.

- **Improve and expedite contract review and negotiation by allowing the AHC to have an on-site representative from the Sponsored Projects Administration and by developing a standard AHC/SPA research agreement for industry-sponsored research.**
- **Establish a Clinical Trials Coordinating Center to coordinate all clinical trials efforts in humans and animals.**
- **Provide support for regulatory compliance monitoring and to expand educational opportunities and information about good scientific practices.**

The task force's work indicates that any plan to help faculty be more competitive in attracting industry-sponsored research must include the seamless coordination of all institutional and regulatory policies, procedures and approvals that affect corporate research. The plan must also include more responsive administrative, oversight, approval, and compliance monitoring services throughout the Academic Health Center.

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