

Academic Affairs

Clinical Research and the Public Trust



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In prior issues of the Journal, I have described clinical research as being a significant component of academics. Additionally, I have emphasized that academics has been and will continue to be a core function of the Ochsner medical institutions. However, just as we have seen headlines in the newspaper highlighting the great accomplishments and additions to science through clinical research, other headlines have raised concerns of conflicts of interests and lack of candor of some investigators.

These concerns have significantly affected the public trust of this important endeavor and need to be discussed. Dr. Jordan Cohen, President of The Association of American Medical Colleges, felt this to be such an important subject that he made clinical research and the public trust the focus of his Presidential Address at the 2000 AAMC annual meeting, where he expertly addressed the pertinent issues.

The hallmark of the issues is the potential and sometimes real conflict of interest of investigators. Conflict of interest is a state, not a behavior. Unfortunately, many perceive a conflict of interest to also signify that there is some sort of ongoing incorrect behavior. In reality, none of us can operate without some sort of conflict of interest. Although conflicts of interest exist in many forms, such as zeal for career enhancement, ego gratification, and self-promotion, it is financial conflict that garners most attention.

Clearly, any subject enrollee in a clinical research or trial program should be aware of all potential conflicts of the investigators. However, as Dr. Cohen pointed out in his presidential address, the academic community needs to strengthen the public trust through appropriate safeguards. Dr. Cohen suggests eight steps to be followed in order to strengthen this relationship.

- The institution should establish policy and be sure that all members comply with disclosure requirements. At the minimum, there should be an annual statement by individuals listing conflicts of interests. This would meet federal minimum requirements.
- Investigator financial interests should be disclosed during the informed consent process. Although there are arguments that the investigators' privacy could be compromised by full disclosure, I believe the prospective volunteers' well-being far outweighs the privacy of the investigators. Additionally, it is the right thing to do.
- There should be institutional consistency in the development and employment of policies to manage conflicts of interests, financial or otherwise. By voluntarily agreeing to abide by a common set of principles, the public will gain confidence with investigators.
- Enlist experts who, although financially tied to for profit enterprises, are involved in "impeccable" research. Looking to successful, reputable experts on our faculties for guidance is a legitimate way to solve this issue.
- Seek a common ground for the upper limits for allowable financial interests. Even with full disclosure of financial ties, upwardly limitless profit sharing by investigators will not help to solidify the public trust in clinical research. The clinical research must be performed as a "public service," not as an open market to increase profits to researchers or institutions.
- Establish a certification process for research faculty. There has been a great deal of work already in this area, and it needs to be extended and institutionalized. By having faculty go through an educational process and then documenting their knowledge base in regards to the myriad of regulations, we can gain greater assurance that our investigators will be acting properly.
- Invest more resources in the institutional research infrastructure. If we are going to be able to be more open, document conflicts, and monitor situations, we need to have the capabilities to be effective. This adds a cost to doing business, and it is a cost that needs to be funded. Ideally, this extra cost should be borne by extramural sponsors, but if that is not readily available then our institutions need to ensure that funding.
- Establish principles governing the institutions themselves in regards to conflict of interest. Although much of the attention has been focused on individual researchers, many of our institutions also have financial interests in this area. These interests need to be clarified and be kept in perspective. The institutions themselves cannot monitor the activities of the investigators if there are significant issues that exist in regards to the relationship of the institutions with for profit entities.

I believe Dr. Cohen's thoughts and ideas are well intended and certainly give each of us pause to reflect, to be sure that we are indeed meeting the needs of the public. I pledge that Ochsner will follow Dr. Cohen's suggestions, to strengthen our public trust.