Federal Demonstration Partnership Phase V
Research Compliance Committee

Monday, September 8, 2008
3:40 p.m. – 4:35 p.m.

The first meeting of the Research Compliance Committee was held to discuss the purpose and scope of the new committee, which has been formed to deal with compliance issues of all types. The Committee will seek to address the administrative components of compliance from both the federal and the institution side. This initial meeting functioned primarily as an information session to enable participants to brainstorm regarding new ideas for streamlining activities.

Over 80 individuals attended the afternoon session, the majority of which were faculty representatives. Ideas for issues to be addressed and approaches to take were discussed. It was agreed that the Committee will need a federal representative that can address administrative issues from a compliance perspective and that we will need to form subcommittees/task forces to address the variety of topics which need to be addressed.

The compliance issues discussed included:

- Human Subjects Compliance
- Animal Care and Use
- Conflict of Interest (individual and organizational; subrecipient conflict disclosures)
- Dual Use Items in Research
- Export Controls
- Costs of Compliance Issues

The two themes of the Phase V Strategic Plan will be addressed by this Committee in the context of research compliance in the following ways:

1. Maximize the time available for Principal Investigators and scientific staff to focus on research by reducing unnecessary burden.
    - Identify practices of member institutions
    - Determine if such practices are absolutely required by the regulations or if some of the rules and practices are self-imposed
    - If the burdensome practices are self imposed, work with membership to identify and adopt the best practices which will minimize faculty effort

2. Increase the efficiency of administrative and compliance practices while reducing inefficient or redundant agency and institutional procedures and practices.
    - Identify practices and agency rules that may be necessary, but which evidence inefficiencies
    - Identify risk level of compliance issues
    - Evaluate the results of surveys which indicate high costs/efforts (including FDP faculty burden survey) as evidence of the burden and/or conduct additional data collection initiatives
    - Determine if practices and rules can be implemented to provide enhanced efficiency by both agencies and institutions through demonstrations. This may be in conjunction with the many professional societies which specialize in certain compliance areas

Initial Ideas of the Group:

A sign-up sheet was circulated to establish a research compliance list serve. This will enable participants to continue communicating our best practices and ideas for topics to pursue as demonstrations.

The group immediately identified a practice that seemed to cause burden to some universities, while others have been able to streamline. First on the list of things to do is to survey practices and submit a matrix of best practices to the membership at our next meeting regarding the confidentiality of human subject participants:

- Tax offices/attorneys requiring social security numbers of human subjects participants even where there is a need for confidentiality. Some universities are told this is unavoidable. Other universities have established procedures to enable the subjects to remain anonymous. Jane Youngers has volunteered to gather the effective management practices so that the schools being forced to operate in this way can see how others have resolved this problem and provide examples to their attorneys.

Topics for further investigation:

- Streamlining IRB approval processes – multi-year approvals; electronic systems; etc.
- Conduct a demonstration to implement a Just-in-Time procedure for certification of IRB approval for other agencies beyond NIH
- Conduct a demonstration to implement a Just-in-Time procedure for approval for use of animals in research
- Certify/license a lab in use of animals rather than require individual letters for each grant
- Change the effective date of an IRB approval to when you begin conducting HS research, not at the time the award is granted
- Develop streamlined conflict of interest processes- expedited evaluations of model disclosures; electronic disclosure reporting for NIH, etc.
- Export controls - deemed exports, maintaining FR, tracking of controlled programs, development of technology control plans
- Dual use items
- Responsible conduct of research

Submitted 9-23-08
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