Responsible Conduct of Research

Preface/Background

The public and regulatory demand for accountability has increased dramatically in the last 20 years. However, regulatory history has largely been as a reaction to abuses and scandals. Regulation of human subjects research began as an outgrowth of Nazi war crimes tribunals (1940's), and a subsequent series of public outcries about abuse of research participants in the early 1960's to mid 1970's. Current practices on ethical standards concerning human participants in research were first codified into law and regulation in 1974. Over 50 years of public debate on animal rights and welfare led to the 1966 Animal Welfare Act, and the Health Research Extension Act of 1985 provided the legislative mandate for the PHS policy pertaining explicitly to research and teaching. Research misconduct came under public scrutiny in the 1970s and early 1980s, eventually leading to regulation. This was followed in the 1990s by regulation pertaining to institutional responsibilities for management of investigators' conflicts of interest.

In 2000, NIH began to define "Responsible Conduct of Research" more broadly and holistically, by announcing a policy requiring that all "research staff" receive complete training in 9 areas of research responsibility by October 1, 2003. Following considerable controversy, the ORI policy was officially suspended in February, 2001. ORI continues to advocate for broad-based research ethics training and sponsors training programs and development of training materials.

In 2001, NIH began requiring RCR training for all NRSA training grant trainees, requiring grantee institutions to submit their training plan for review prior to issuance of an award. Then the 2007 America COMPETES Act, requires that

> *"Institutions that apply for financial assistance … for science and engineering research or education [from the National Science Foundation] should include a plan in their grant proposals for appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers who will participate in the proposed research project."*

Clearly, requirements from all federal agencies for a comprehensive institutional plan for RCR training are not very far away.

Core Areas of responsible research practices

--as identified and defined by US Office of Research Integrity (ORI)

- *Data Management* – practices related to collection, storage, protection, ownership and sharing of data.
- *Conflict of Interest/Commitment* – standards to ensure there is no reasonable expectation that design, conduct or reporting of research will be biased by any conflicting financial interest of a researcher.
- *Human Subjects* – regulation of research using human participants to ensure risks do not outweigh benefits and that the rights of the participants are respected.
- *Animal Welfare* – standards for the humane care and use of animals in teaching and research.
- *Research Misconduct* – fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results.
- *Publication Practices and Responsible Authorship* – assurances that research results preserve the public trust and protect the public health.
- *Mentor/Trainee Responsibilities* – the social foundation of research as an essential element of research training which guides research conduct, management and ethics.
- *Peer Review* – assurance of accuracy and significance of published reports of findings and protection for the reputations of authors.
- *Collaborative Science and the Resolution of Disputes* – guidance for shared "ownership," responsibilities and (perhaps) funding for common project.
- Other issue areas include:
    - Questionable Research Practices
    - Social Responsibility of researchers
    - Cross-disciplinary Research