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.

public debate on animal rights and welfare led to the 1966 Animal Welfare Act, and the <u>Health Research Extension Act of 1985</u> provided the legislative mandate for the <u>PHS policy</u> 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, <u>requires</u> that

11

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