Clemson University research compliance committees (ARC, IBC, and IRB) have regulatory responsibility for review and oversight of research, teaching, or testing activities even after initial approval. There are several mechanisms used to accomplish post-approval follow-up, including, but not limited to, annual reviews/continuing reviews, Office of Research Compliance (ORC) contacts, spot monitoring, semi-annual reviews, complaint investigations, self-evaluations, etc.

The Clemson University ORC has refined its post-approval follow-up program to include announced visits with principal investigators to assess compliance with approved protocols and to provide an additional opportunity for communication between the ORC and the investigator. This program has been developed to contribute to this important oversight requirement. The overarching intent of the program is to provide assurance to regulatory agencies and to Clemson University that research is monitored for compliance with approved protocols. Receiving a follow-up visit does not imply non-compliance or wrong-doing is suspected in the conduct of the study. The goal of the program is to help researchers achieve and maintain compliance. Post-approval follow-up is essential to ensure the well-being of human subjects, animals, and staff, to ensure that activities are conducted in compliance with the regulations and standards of State and federal agencies, and to ensure that activities are consistent and conducted in compliance with Clemson University approved protocols and policies. This process will also allow the ORC to conduct a review of its own processes and identify areas for improvement. This post approval follow-up activity does not substitute for any of the other existing inspection programs.

The post-approval follow-up process will include visits with the PI/research team to evaluate record keeping, training records and hazard storage and handling, observe or discuss how procedures are being performed, and discuss approved activities. A mutually agreed upon date will be set for the visit and the PI will be provided with a set of questions in advance that will serve as the focus for the follow-up visit. As much as possible the follow-up visit will be timed to coincide with the annual review or a semi-annual inspection so that duplication is minimized. Criteria for selection of which protocols are to be reviewed may include, but not be limited to, type of protocol and initial review, significant personnel changes, adverse incidents/events, level of risk to human subjects or to staff, or potential for pain and distress to animals.

Approximately 3-5% of the active protocols will be included in the pilot. Plans of action will be developed for any problems or issues noted on these visits and further education provided, if applicable. Anticipated start date for this program is September 2006. If you have any questions, please contact our office at (864) 656-1525.