APPENDIX B
NON-COMPLIANCE POLICIES AND PROCEDURES
Developed and approved by the UCO-IRB-February13, 2009

1. Policy

The goal of the UCO-IRB is to promote research and protect subjects, researchers, students, and the university. The role of the IRB is to insure that all UCO-associated research activities comply with the regulations set forth by the Department of Health and Human Services Code of Federal Regulation Title 45 Part 46. To that end, it is the responsibility of the IRB to insure that the approved protocols are followed and that subjects' rights and privacy are protected.

If the IRB receives a report that non-compliance or misconduct has occurred, it is obligated to act on the allegation. The Chair is required to conduct an investigation and report the findings to the IRB Board at the next meeting. The Board must then determine if the allegation has been proven, if so, the degree of seriousness of the violation, and the appropriate sanctions or actions. The results of the investigation and sanctions are then reported to the Provost and other appropriate administrators or officers.

2. Definitions

Non-compliance is defined as a failure to follow IRB policies which can include:

- not applying for IRB approval prior to involving humans as subjects in research activities
- not obtaining final IRB approval for a project prior to engaging humans as subjects in research activities
- not following an approved protocol or application
- making changes in procedures, personnel, recruitment, number or type of subject groups, or Informed Consent Forms without prior approval
- not obtaining Protection of Human Research Subjects training certification before beginning research involving human subjects

3. Sanctions or corrective actions

Sanctions or corrective actions are based on the seriousness of the violation and the degree of risk to subjects that has resulted. Sanctions or corrective actions can include (but are not limited to) the following:

- temporary suspension of some or all research activities
- prohibition of further use of the data
- prohibition of future on-campus research funding
- prohibition of mentorship privileges
- required completion of on-line research ethics training
- formal acknowledgement of violations and assurance of future compliance
- informing appropriate administrative personnel
- violation report to funding agency
- preparation of IRB application or other forms
- modifying the protocol or Informed Consent Form
- requiring current subjects to re-consent to the project
- modifying the continuing review schedule
- terminating the research project