**Policy on Non-Compliance**

Non-compliance means failure by an investigator to abide by the University, State, and Federal regulations protecting animal subjects used in research, teaching, and outreach programs. Instances of non-compliance would include beginning research before securing IACUC approval, intentional misuse or non-use of approved forms (animal use forms, consent forms for research with donated or previously owned animals, amendment forms or exemption forms), failure to secure IACUC approval for an amendment before introducing changes in an on-going protocol, and continuing to gather data from subjects after IACUC approval expires. Non-compliance with IACUC policies is a violation of Central Michigan University’s policies, NIH Assurance, and State and Federal regulations for the protection of animals used in research, teaching, and outreach. Incidents of non-compliance must be reported to the IACUC both to ensure the protection of the animal subjects and to uphold the Central Michigan University Assurance A4076-01 to the Federal government.

Non-compliance presents a serious challenge to the IACUC regardless of investigator intent; unapproved research involving animals places the University research, teaching and outreach programs and the animals at an unacceptable risk. Any incident of non-compliance with IACUC guidelines must be reported to the Chair of the IACUC immediately.

The IACUC will promptly investigate reported instances of non-compliance, and may require suspension of research or teaching while it does so. Upon receipt of information indicating possible non-compliance, the Chair advises the investigator(s) that a non-compliance review has been initiated by the IACUC depending upon the complexity and seriousness of the possible non-compliance. The Chair may conduct the investigation through discussions or correspondence with the responsible investigators or the IACUC may impanel an investigative subcommittee. In the latter instance, the subcommittee reviews the evidence and makes recommendations to the full committee. The investigator(s) are invited to submit in writing their account and explanation of the events constituting possible non-compliance. At his/her request, the investigator(s) may also appear before the IACUC on a case-by-case basis. At their request, the investigator(s) may be accompanied, or represented by faculty or legal counsel in presenting arguments to the full committee. Or, the investigator(s) may have a member of IACUC, typically a representative from their college, present arguments on their behalf to the full committee.

When, after deliberation, the IACUC determines that non-compliance has occurred, it will take appropriate action to protect the welfare of animal subjects. In the case of serious or continuing non-compliance the IACUC and the University will address the question of when the investigator(s) research or teaching can be continued. The IACUC will also take remedial action, as necessary, regarding the welfare of the research animals and the research data gathered in non-compliance. IACUC will refer instances of serious non-compliance to an appropriate administrator who must decide whether to impose disciplinary sanctions. The distinctions between remedial action taken by the IACUC and disciplinary action taken by an administrator is: Remedial action is action that the IACUC takes or may require on behalf of present or future animal subjects of research, teaching or outreach; Disciplinary action, in this context, is a penalty imposed by administrators on an investigator for serious non-compliance with the regulations protecting animal subjects of research, teaching or outreach.

In addition, Federal Policy (AWAR §2.31,d,7; PHS Policy IV,C,7; IV,F,3) mandates that any serious or continuing non-compliance with IACUC determination and/or other Federal and State regulations promptly be reported by the Institutional Official (IO) to the Office of Laboratory Animal Welfare (OLAW) and USDA/AC. The Public Health Service and other Federal agencies may require that the University return part or all of the funding of the project and may impose future restrictions on the University and the investigator impacting the ability to obtain Federal funding for animal research and teaching.

An investigator who believes the IACUC has erred in its finding of non-compliance may submit a written request asking IACUC to reconsider. The request should clearly indicate the facts or the IACUC interpretation in dispute, providing supporting evidence where applicable. In all non-compliance reviews the IACUC provides notice to investigator(s) of its determinations and remedial actions, if any. If the IACUC determines that the non-compliance was sufficiently serious to warrant the consideration of disciplinary sanctions (as opposed to remedial actions
intended to protect subjects or the integrity of the research environment), it will forward that recommendation to the IO in the Office of Research and Sponsored Programs. No one in the University may approve research that has been disapproved by IACUC (AWAR §2.31, d, 8; PHS Policy IV, C, 8). Investigator(s) who believe the IACUC has acted contrary to provisions of AWAR, Federal, or University policies or contrary to terms of its Assurance to the Federal government (A4076-01) may contact the Office for Laboratory Animal Welfare at NIH at (301) 496-7163 and/or the USDA APHIS Animal Care, Eastern Regional Office at (919) 855-7100.