



University of Pittsburgh

Research Conduct and Compliance

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MEMORANDUM

TO: The University's Research Community

FROM: Randy P. Juhl, Ph.D. 

DATE: November 8, 2005

SUBJECT: Good Laboratory Pactices (GLP) vs. good laboratory practices

I am writing to call your attention to a problem that has surfaced with increasing frequency and that has the potential to cause much anguish for the affected investigators. The FDA has established a set of very rigorous performance standards for nonclinical laboratory (animal) research conducted to determine the safety of articles (e.g., potential drugs or devices) that will be subject to regulation by the FDA. These standards are referred to as current Good Laboratory Practices (GLP) and are defined in the Code of Federal Regulations Title 21, Part 58. Good Laboratory Practice For Nonclinical Laboratory Studies, http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr58_01.html

At the present time, there is no laboratory facility or research group at the University of Pittsburgh that is certified to conduct nonclinical laboratory (animal) research studies in accordance with GLP standards. That is not to imply that we do not do good work or do not adhere to conventional laboratory standards for the basic science research we conduct. However, even a cursory review of the GLP regulations will reveal the extra effort and substantial resources required to meet the GLP standard.

At some time in the future, establishment of a GLP facility may be contemplated, but because we do not now have GLP certified facilities or processes, we cannot accept contracts to perform GLP work. Therefore, from here forward, the Office of Research will insert a statement all contracts for animal research studies conducted on behalf of private sponsors that will explicitly inform the sponsor that the University will conduct the research according to generally accepted academic research standards but will not operate at the GLP level. Furthermore the sponsor must agree that the data generated from the research may not be submitted for any regulatory filing that requires a certification of GLP compliance.

If you have questions about this topic as it relates to the negotiation of new contracts, please contact Kelly Downing in the Office of Research (412-624-7419; kdowning@offres.pitt.edu).

If you are unclear about implications described herein related to research that you have already agreed to perform, please contact Dr. Ed Kennah in the IACUC Office (412-383-2014; ekennah+@pitt.edu). It would be far better to clarify expectations now rather than attempting to do so after the work is done and the FDA is on their way to audit your laboratory.

Thank you for your attention to this issue.