RESEARCH COMPLIANCE GUIDANCE, OCTOBER 2020

WHAT YOU NEED TO KNOW BEFORE MAKING COMMITMENTS ABOUT GOOD LABORATORY PRACTICES

Following Good Laboratory Practices (GLPs) means more than practicing good science when conducting research experiments. GLPs describe how nonclinical laboratory studies should be planned, performed, monitored, recorded, reported, and archived as set forth by the U.S. Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and U.S. Department of Agriculture (USDA), as well as the Organization for Economic Co-operation and Development (OECD) international guidelines. The requirements are complex and meeting GLP standards is stringent, costly and burdensome.

GLPs apply when conducting in-vitro or in-vivo safety studies and in some cases efficacy studies on certain regulated products. Some examples include:

- Non-clinical laboratory studies that support or are meant to support applications for research, or marketing permits for products regulated by the FDA, including food and color additives, animal feed additives, human and animal drugs, medical devices for human use, biological products, and electronic products (see, 21 CFR Part 58).

- Studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA (see, 40 CFR Part 160).

- Studies relating to health effects, environmental effects, and chemical fate testing of chemicals that are regulated under the Toxic Substance Control Act, including but not limited to polychlorinated biphenyls, asbestos, radon and lead-based paints (see, 40 CFR Part 792).

Texas A&M University does not maintain a GLP program to support compliance with GLP regulations. Therefore, it should not agree to terms and conditions requiring certification of GLP compliance. If an investigator has an interest in conducting GLP related work, the office conducting the contract negotiations (i.e. SRS) should be consulted first to determine what, if any, terms and conditions may serve as an appropriate alternative (i.e. sponsor has ultimate responsibility for GLP compliance, and the work is being conducted at a facility operated and under the sponsor's oversight and control).