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To: FAU Research Community

From: Dr. Daniel Flynn, Vice President for Research

Re: FDA Regulated, Investigator Initiated and Phase 0-I Industry Sponsored Clinical Trials at FAU

This memorandum serves as an official document and puts into writing the decision related to Florida Atlantic University (FAU) not engaging in U.S. Food and Drug Administration (FDA) regulated, investigator initiated clinical trials and phase 0 and I industry sponsored clinical trials.

FAU faculty and students conduct a diverse array of human subject's research projects. Some of these research studies may be classified as clinical studies or clinical research and may fall under the FDA and Department of Health and Human Services (DHHS) regulations. Studies involving human subjects involving drugs, devices or biologics must be in compliance with relevant FDA and DHHS laws and regulations, and investigators designing and implementing clinical studies need to be aware of these FDA and DHHS regulations.

There are two types of clinical trials: industry sponsored and investigator initiated. Both types typically include an external funding source and FAU faculty investigators, however the most significant difference between the two types of studies is where the responsibility for primary legal and ethical requirements fall.

In **industry-sponsored studies**, the sponsor (e.g. pharmaceutical company) is the party who takes responsibility for and initiates the clinical investigation. According to the FDA and all regulatory bodies, the sponsor has the responsibility for designing, conducting and overseeing the study to ensure compliance with all legal and ethical requirements. This includes safety monitoring, FDA requirements, investigational product, scientific merit, conflict of interest, adverse patient events, etc. FAU is currently able to accommodate Phase II-IV industry sponsored studies through the Clinical Translational Research Unit (CTRU).

In **investigator-initiated studies**, FAU is the party that takes responsibility for and initiates a clinical investigation (investigator designs the study) assuming responsibility for the legal and ethical requirements identified above. In this scenario, when the research is also FDA regulated, the responsibility and liability exposure to FAU is potentially very high. Clinical trials are expensive, and in those cases when costs cannot be borne by the granting agency, they become the responsibility of the unit proposing the study.

For all clinical trials there is a significant concern about providing medical treatment when a study subject has an adverse event related to the study. Medical schools with teaching hospitals have their medical staff typically cover these costs, in the absence of a teaching hospital, FAU must determine how we will address this issue for clinical trials. This is a critical aspect that must be resolved and codified in policy prior to the advancement of these high risk clinical trials.

As FAU continues to grow the research infrastructure and establishes a clinical trials administrative unit, the university will then be able to expand its scope to conduct FDA regulated investigator initiated and Phase 0 and I clinical trials.