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Policy statement

All clinical trials conducted at The University of Toledo (“University”) are subject to internal audit inspections, including those trials sponsored by pharmaceutical and/or device companies, NIH, other sponsors, and those that are investigator-initiated. The Jacobson Center for Clinical and Translational Research (JCCTR) is responsible for conducting and overseeing the internal audit compliance program.

(B) **Purpose of policy**

The primary purpose of the internal audit process is to ensure the protection of human providing an increased awareness of University policies to researchers and staff as well as education of best practices to ensure the University is conducting consistent high quality research.

(C) **Scope**

Internal audits will be categorized as: targeted, for-cause, and informal audits that are performed to assist in preparations for a scheduled or anticipated inspection by the FDA or sponsor. Targeted audits are routine and selection is based on prioritized set criteria [see section (D)(1)] which includes those with an increased likelihood for an external audit (e.g. high enrollment) or a specific category of research such as gene transfer research. For-cause audits can be initiated at the request of the IRB, research

administration, or some other group or person who has raised substantive concerns regarding study conduct. Informal audits can be requested by Principal Investigator (PI) or research staff and is dependent upon current work flows and resource availability and schedules.

(D) **Targeted Internal Audit Procedures**

(1) The internal audit process begins with

- (e) Lab and diagnostic testing have been performed per protocol requirements

- (8) Documentation of all internal audits along with PI and IRB/University officials' response (if applicable) will be kept confidential to the extent permitted by law and maintained in the JCCTR Internal Audit files.

Approved by:

/s/

Christopher J. Cooper, MD
Executive Vice President for
Clinical Affairs
Dean of the College of Medicine &
Life Science

August 10, 2018

Date

Review/Revision Completed by:

SLT

*Vice President for Research
Director, Jacobson Center for
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