Name of Policy: Internal Auditing of Clinical Research Policy **Policy Number**: 3364-70-28 **Approving Officer**: Executive Vice President for Clinical Affairs **Responsible Agent**: Director, Jacobson Center for Clinical and Translational Research **Scope**: All UT campuses	**Original effective date**: August 8, 2018
Key words: Internal audit, monitoring procedures, regulatory compliance, protocol adherence	

☒	New policy proposal	☐	Minor/technical revision of existing policy
☐	Major revision of existing policy	☐	Reaffirmation of existing policy

(A) **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 subjects, verify the validity and accuracy of data collection, identify non-compliance, and take corrective action when necessary. The audit process involves verifying subject eligibility, protocol adherence, and regulatory compliance according to FDA, ICH Good Clinical Practice, University policies, and all other applicable regulations. The internal auditing of clinical trials will promote continuous improvement opportunities by 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 selecting a study protocol to audit. Set criteria are used to prioritize all active clinical research studies: new investigators and/or research coordinators, number of subjects enrolled, sponsorship, disease site, and complexity/high-risk studies.

(2) The Clinical Research Auditor will coordinate all internal audits. The PI and research staff will be sent a notification letter via email that contains the following:

(a) The study title/protocol that will be audited

(b) The agreed dates the auditor will be on site

(c) That ALL subject records need to be up-to-date and available. The auditor will *randomly select* which subjects will be audited during the visit.

(d) A copy of the FDA Audit Preparation Guidance for Clinical Investigations checklist that highlights what regulatory documents the auditor will be reviewing throughout the internal investigation. The PI is responsible for ensuring that those documents highlighted on the checklist are available during the departmental inspection.

(3) The Clinical Research Auditor will coordinate a date and time to meet with the Investigational Pharmacist (if applicable) to review all study drug accountability and dispensing records.

(4) The Clinical Research Auditor will complete an audit review form on every subject monitored during the inspection. The following elements will be reviewed:

(a) Informed Consent Form (ICF) and documentation of the consent process

(b) Subject eligibility and screening compliance

(c) Protocol required procedures/visits are complete

(d) Adverse and Serious Adverse Events have been properly reported to sponsor/IRB

(e) Lab and diagnostic testing have been performed per protocol requirements
(f) Data collection is attributable, legible, contemporaneous, original and accurate (ALCOA standards for GCP)

(5) Exit Interview: The PI and key study staff will attend the exit interview or notify the Clinical Research Auditor of the need to reschedule the exit interview. Any rescheduled exit interview must occur without delay. The Clinical Research Auditor will present the findings from the audit and respond to any questions from the PI or research team at the end of the inspection. This is an opportunity for the PI to discuss any issues of non-compliance or other identified issues and provide appropriate clarification.

(6) The Clinical Research Auditor will complete a formal internal audit report after the inspection and provide a copy to the PI within ten (10) business days. The auditor will evaluate the areas of study conduct that include human subject protections, protocol and regulatory compliance, validity and accuracy of data, drug and/or device accountability and will assign a preliminary internal audit rating at the conclusion of the inspection. The Clinical Research Auditor may notify the reviewing IRB and/or the appropriate University official(s) of any findings as necessary for the protection of human subjects or compliance with University policies. The PI will have fifteen (15) business days to respond back to the Clinical Research Auditor. Copies of the final internal audit report will go to the Dean of the relevant college, the VP of Research, and the Executive Director of Internal Audit and Chief Compliance Officer.

(7) Internal Audit Ratings:

(a) Exceptional: evidence of consistent GCP compliance.

(b) Acceptable: only a few minor deviations noted.

(c) Deficient: major protocol violations identified. Requires a written corrective action plan from the PI addressing all areas that require improvement within ten (10) business days.

(d) Unacceptable: requires immediate action and a written response from the PI within five (5) business days, including the specific date by which the compliance plan will be fully implemented. The Clinical Research Auditor will immediately notify the appropriate individuals such as the IRB Chair or designated IRB contact person, VP of Research, and/or the Dean of the relevant college of any suspected human subject safety issue(s) and/or any potential fraud or fabrication violations. The IRB or University officials may take immediate action including suspending enrollment or closing the study, if deemed necessary.

(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 Clinical and Translational Research*	**Policies Superseded by This Policy:** • *n/a* Initial effective date: August 10, 2018 Review/Revision Date: n/a Next review date: August 10, 2021