Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**
Date Created: **November 14, 2023**
Title: **Review of Laboratory Results**
Version Date: **November 14, 2023**
SOP Number: **SM44**

PURPOSE:
The purpose of this standard operating procedure (SOP) is to outline the process for the review and documentation of both local and central research laboratory results.

SCOPE:
This SOP applies to all clinical trials led by Principal Investigators and managed by staff at the University of Nebraska Medical Center.

PERSONNEL RESPONSIBLE:
Principal Investigators (PI), Sub-Investigators, coordinators, and regulatory staff are responsible for ensuring the review and documentation of research laboratory results.

DEFINITIONS:
- **Clinically Significant**: A result that requires additional active management and/or further evaluation.
- **Documentation**: All records, in any form (including, but not limited to written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting research, and the actions taken.

PROCEDURES:
A. The Principal Investigator or an approved sub-investigator reviews all available laboratory results from the protocol mandated tests.
    a. Results obtained outside of protocol requirements may be reviewed at the Investigator's discretion.
B. All local laboratory results and any necessary action taken will be documented in the electronic medical record. The Investigator will not be required to specifically state whether each result is or is not clinically significant.
C. If any action is taken (i.e., treatment, additional or follow up laboratory assessments), the result will be assumed to be clinically significant and reported as such per protocol requirements. The investigator and coordinators are responsible for communication of this action to ensure proper documentation.

RESOURCES:
- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1). Guidance for Industry. (2018, March)

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Department Approval

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Signed Date: 11/14/2023

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