THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

College of Medicine

Office of Research

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Memo

Date: March 18, 2020

To: Study Sponsor/CRO

From: Frank White, Director of Research Compliance
           Alana Mahley, Regulatory Manager

RE: INFORMATION IN RESPONSE TO 21 CFR 11 REQUEST

The Ohio State University Wexner Medical Center is committed to maintaining the privacy and security of patient information and has appropriate processes in place to promote compliance with applicable regulations and institutional policies. The Wexner Medical Center utilizes an electronic health record system which may contain electronic source data for clinical research studies. The system primarily utilized is Epic, which has adequate policies and procedures in place for system maintenance and validation.

Users must meet specific requirements to access the system, including documented training. Users granted access to the system will have a unique identification that is not reassigned to other users and a confidential password that must be changed at regular intervals and not shared with other individuals. The system does have an audit trail record to identify the individual accessing the system and the date and time of any change made to the record. The system also has the ability to generate electronic authentication based upon the unique ID and confidential password of the user.

Research sponsors and sponsor monitors may be granted access to the medical records to verify source data. At least ten (10) business days' notice is required to accommodate such access requests. Monitors will be given their own unique login and password. Access will be limited to viewing only those records of subjects who have signed the clinical trial consent and HIPAA authorization form to participate in the research study.

For additional information, please contact Frank White, Director of Research Compliance (Frank.White@osumc.edu) or Alana Mahley, Regulatory Manager (Alana.Mahley@osumc.edu).