UNIVERSITY OF MIAMI

UNIVERSITY OF MIAMI POLICY AND PROCEDURE MANUAL

TITLE:	Purchasing Computerized Systems and Software Applications for Clinical Research	REFERENCE:	Revised
CATEGORY:	Information Technology	PAGE:	1
		SUPERSEDES:	POL-UMIT-PUR-017-02
APPROVER:	David Ertel Interim Senior Vice President Business and Finance	VERSION: EFFECTIVE:	3 March 1, 2017

Information Security exists to further the mission of the University. The University is comprised of large and diverse populations with evolving needs related to information technology resources and data. University management is committed to safeguarding those resources while protecting and promoting academic freedom. Although intrinsic tension exists between the free exchange of ideas and information security, and can manifest itself in some circumstances, the requirements that follow have been identified to promote the best balance possible between information security and academic freedom.

I. PURPOSE:

Clinical research studies are subject to federal, state and local regulations as well as audits/inspections by these agencies. FDA 21 CFR Part 11 regulations require that electronic records and electronic signatures used in clinical research meet specific criteria. In addition, the FDA has issued guidance documents for the use of computerized systems in clinical investigations. The term computerized system applies to records in electronic form that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required by the FDA to be maintained, or to be submitted to the FDA. This policy is being implemented to ensure that only compliant computerized systems and/or software applications are purchased and installed for use in clinical research that is subject to 21 CFR Part 11 regulations.

II. SCOPE:

This policy applies only to FDA-regulated clinical research at the University. Prior to purchase, all computerized systems and/or software applications that may be used in support of FDA regulated clinical research at the University must be evaluated for compliance with regulatory requirements. This applies to all new computerized systems and/or software applications as well as custom developed applications and version upgrades to be purchased or contracted. This evaluation will be conducted by the Clinical Research Electronic Data Committee or designee who will provide an assessment of the system/software in question, based on FDA regulations 21 CFR Part 11, 312, and 812 as well as FDA guidance documents (See References).

Computerized systems and/or software applications must have documented approval for use in FDA-regulated clinical research by the Clinical Research Electronic Data Committee or designee prior to purchase.

Non-adherence with policy requirements may result in sanctions to individuals and/or departments, up to and including loss of privileges to conduct clinical research.

III. POLICY:

University personnel who are considering the purchase of a new or custom developed software application or computerized system for use in clinical research that is subject to 21 CFR Part 11 regulations must follow these steps prior to purchasing or entering into a vendor agreement with another company.

1) Contact the Clinical Research Electronic Data Committee (CREDC) to schedule an assessment:

   Office of Chief Information Security Officer: ciso@miami.edu

2) Obtain a written assessment from the CREDC or designee regarding the software/computerized system's compliance with 21 CFR Part 11 requirements. Note that this assessment may include recommendations to mitigate certain deficiencies.

3) If deficiencies from 21 CFR Part 11 are found, customization or specific configuration may be required.

4) Communication with the vendor and the CREDC or designee should continue until the deficiencies are resolved or mitigated, if possible.

5) If the software/computerized system has the capability of meeting the requirements of 21 CFR Part 11 regulations and is deemed acceptable for use in clinical research at the University, obtain written approval from the CREDC and proceed with the standard purchasing process.

6) If the software/computerized system does not have the capability of meeting the requirements of 21 CFR Part 11 regulations; an alternative will be required. The CREDC or designee will document the software/computerized system's deficiencies in the assessment.

IV. DEFINITIONS:

Computerized System: A computerized system includes computer hardware, software, and associated documents (e.g., user manual) that create, modify, maintain, archive, retrieve, or transmit in digital form information related to the conduct of a clinical trial subject to FDA regulation.

Principal Investigator: An individual who actually conducts a clinical investigation and under whose immediate direction the investigational drug or device is administered, dispensed or used.

RCQA: The office of Research Compliance & Quality Assurance

Software Application: A program or group of programs designed for end users to perform specific tasks. Examples are: UChart, IRB-7, Excel, etc.

Sponsor: A person who initiates, but does not actually conduct, the investigation; that is, the investigational drug or device is administered, dispensed or used under the immediate direction of another individual.

Sponsor-Investigator: An individual who both initiates and conducts a clinical investigation and under whose immediate direction the investigational drug or device is being administered, dispensed or used.

V. PROCEDURE:

The following parties are responsible for the compliance and governance of this policy:

- Office of the Vice Provost for Research;
- Office of Research, Research Education and Innovative Medicine;
- Office of Research Administration;
- Research Administrators;
- Research Compliance and Quality Assurance;
- Information Technology;
- Purchasing;
- Sponsors;
- Sponsor-Investigators;
- Principal Investigators;
- Division Chiefs;
- Department Chairs and Administrators;
- Study team members.

Enforcement:

Vice Provost for Research or designee and Chief Information Officer (CIO) or designee are responsible for monitoring the enforcement of the policy.

Sanctions:

N/A

References:

- FDA 21 CFR Part 11: Electronic Records; Electronic Signatures
- FDA 21 CFR Part 312: Investigational New Drug Application
- FDA 21 CFR Part 812: Investigational Device Exemptions
- FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application, August 2003
- FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, May 2007