

<b>UMCIRB Correspondence: Electronic Signatures</b>	Effective Date	6.28.2012
	Revision Date	9.1.2019

- 1.0 Purpose:** This Standard Operating Practice (SOP) establishes the position of the University and Medical Center Institutional Review Board (UMCIRB) regarding signatures on IRB approval letters. The UMCIRB utilizes an electronic submission system (ePirate) for all UMCIRB submissions. As such, there are no handwritten signatures or printed paper approval letters generated from the UMCIRB regarding decisions/approvals. All signatures for decisions and approvals in ePirate are recorded electronically in the closed access submission system.
- 2.0 Research Protocols Affected:**
- 2.1 Human subject research reviewed and approved by the UMCIRB.
- 3.0 Rule:** This rule is to ensure that users and sponsors/funding agencies are aware of the security standards within ePirate for electronic signature. ePirate is an electronic IRB submission system that is designed to support 21 CFR Part 11 requirements for a closed access system.
- 4.0 Definitions:**
- 4.1 Closed access system: data is maintained within the same institution that governs the process.
- 5.0 Responsibilities:**
- 5.1 ePirate Users will ensure their ePirate username and password are physically protected by securing this information so no one else could gain unauthorized access.
- 5.1.1 ePirate users will ensure appropriate selection of responsibilities upon registration.
- 5.2 UMCIRB office will ensure appropriate ePirate role assignment for all users according to their research responsibilities.
- 5.2.1 Roles enforce appropriate signature actions and workflow specific access.
- 5.2.2. Multiple roles can be assigned to a user based on their responsibilities.
- 5.3 UMCIRB Administrative Director or designee will ensure compliance with this policy within the UMCIRB office by ensuring all staff are trained in the proper procedures for initializing ePirate profiles.
- 6.0 Procedures:**
- 6.1 All users will register in ePirate and designate the responsibilities they will have in the conduct of human research.
- 6.2 Upon receipt of registration information, UMCIRB staff will create the user profile which assigns specific role(s) to the user.
- 6.3 Each time the user logs in to ePirate, the username and password for the system will be required.
- 6.3.1 If user has multiple roles, they will choose the role they are performing an action for from the options on the Dashboard screen of ePirate.
- 6.4 Every action taken by that user is automatically recorded in the history of the appropriate workspace.

**Revision History:**

<b>Date</b>	<b>Change</b>	<b>Reference Section(s)</b>
9.1.2019	Update office name throughout; clarify use of Dashboard in ePirate instead of My Home (old term used in previous version of ePirate)	Sections 1, 3, 5, 6; 6.3.1

**References**

FDA. Code of Federal Regulations, 21CFR11—Electronic Records, Electronic Signatures:  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=11>