Office of Clinical Research (OCR)

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Responsibility: OCR		Page 1 of 1
Policy 1.7.1		

INSTITUTIONAL REQUIREMENTS FOR PERSONAL DIGITAL CERTIFICATES

1. PURPOSE: This policy establishes the process and procedure for obtaining a personal digital certificate for use in electronic submission to FDA for INDs or IDEs.

2. POLICY: The Office of Clinical Research (OCR) will require that any of the employees in the Research Protection Program that assist Principal Investigators with electronic submissions of INDs or IDEs to the Food and Drug Administration (FDA) via the Electronic Submissions Gateway (ESG) will act pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations to utilize their electronic signatures as the legally binding equivalent of a traditional handwritten signature. A digital certificate with an expiration date of 1 or 3 years will be obtained through Information Security to be used for electronic FDA submissions. The certificate will be deactivated upon employee termination from the university, regardless of expiration date on the certificate.

3. PROCEDURE: A letter of Non-Repudiation Agreement for digital signatures must be submitted to the FDA prior to registering as a transaction partner for the FDA ESG https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/AboutESG/ucm113964.htm. This letter must be submitted on the institutional letterhead and signed with a traditional signature, or signatures, if there are multiple applicants and by their supervisor, and by the appropriate institutional official. This document will be sent electronically to ESGHelpDesk@fda.hhs.gov, and in addition the physical copy itself will be sent to the FDA within 2 weeks of the electronic copy.