



Nova Southeastern University
Standard Operating Procedure for GCP

Title: <u>Archiving Changed SOP's</u>		Version # 1
SOP Number: OCR-ACS-001	Effective Date: August 2013	Page 1 of 2

PURPOSE: Standard Operating Procedures are an ongoing process that requires adjustments related to the changing environment at the Center/College. The purpose of this SOP is to describe the process to archive the SOPs that have been updated.

POLICIES:

1. When an SOP needs to be changed the site staff should print a copy of the current SOP and store the copy in archived documents.
2. Staff should then access the current SOP to be changed in the word directory following guidelines in OCR-ADM-001, do the required edits, rename and save the changed file eg; (change OCR-ADM-001 to OCR-ADM-001.1)
3. The new file should then be printed and placed in the appropriate section of the SOP binder.

References:

21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.68	Inspection of investigator's records and reports
FDA Information Sheets, October, 1995	Recordkeeping in Clinical Investigations
May 9, 1997 International Conference on Harmonization;	Good Clinical Practice: Consolidated Guideline