



**Nova Southeastern University  
Standard Operating Procedure for GCP**

<b>Title: <u>Guidelines for Writing Notes to the Study File</u></b>		<b>Version # 1</b>
<b>SOP Number: OCR-ED-004</b>	<b>Effective Date: August 2013</b>	<b>Page 1 of 3</b>

**PURPOSE:** Notes to the Study File are written to identify a discrepancy or problem in the conduct of the clinical research study, note the root cause of the identified problem, identify the corrective action taken to prevent recurrence of the problem, and document that the corrective action has resolved the problem. In general, the tone of the note should be forward-looking and not seek to explain an error discovered in the conduct of a clinical research study. For example, a Note to Study File may be appropriate to:

1. Clarify or add information regarding site specific regulatory file requirements,
2. Clarify or add information regarding source document standards,
3. Document and address any issue that is protocol- and/or site-specific that cannot be resolved without a change from previous procedures.

**POLICIES:**

1. Note to the Study File should be printed on institution letterhead and it should be initiated and authored by the individual or organization responsible for its content, as follows:
  - 1.1 If the issue relates to site performance, the appropriate credentialed individual from the site should write and sign the note to file.
  - 1.2 If the issue relates to PI responsibilities (e.g., human subject protection, data integrity at the site), the PI should write and sign the note to file.
  - 1.3 If the issue relates to actions taken by the sponsor or monitor (e.g., clarification of a protocol section), an appropriate credentialed individual from the sponsor should write and sign the note to file.

2. Retention and Distribution

2.1 All Notes to the Study File should be signed by the author, kept on file in the site regulatory file and made available to the clinical site monitors reviewing the site's documents and procedures.

2.2 Note to the Study File Template (see attached guideline template)

## <Institution Letterhead>

- Date:** <Date that the Note to the Study File is written>
- To:** <NIDCR Protocol number followed by "Study File">
- From:** <Name, title, and the site or institutional affiliation of the person authoring the Note to the Study File, and this individual's signature>
- Issue:** <Brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list, or bulleted items>
- Root Cause:** <The reason(s) that the issue arose>
- Corrective Action:** <Description of the corrective actions taken or planned by the site personnel. If the site was instructed to perform these corrective actions (i.e., by the sponsor or monitor), indicate by whom and as of what date. If status of reports, records, or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed.>
- Resolution:** <Description of the procedures used to document resolution of the problem.>
- Effective date of resolution:** <Effective date for corrective action (may be the same date as in the memo header)>
- Comments:** <Any additional comments or information not noted above>