



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

<u>Title: Credentialing of Physicians or other Staff to Do Research</u>		<u>Version # 1</u>
SOP Number: OCR-GEN-001	Effective Date: August 2013	Page 1 of 2

PURPOSE: Prescribing investigational treatments or being involved in research calls for a more restrictive background check than the usual standard of care.

POLICIES:

1. No individual may engage in research activity without being properly credentialed by the Center/College.
2. The scope of general credentialing shall equivalent to the work expected to be performed. For example, if the bylaws require a Board Certified Specialist for performing protocol related procedures, but the researcher does not have appropriate qualification, the Board Certified Specialist should be included in the research team.
3. The reported FDA history pertaining to debarment, disqualification, assurances or restrictions shall be verified.

Procedures For FDA Background Check

1. The credentialing staff shall assure that the researcher is not DEBARRED from prescribing investigational agents as evidenced by not being on the FDA Debarment List located at http://www.fda.gov/ora/compliance_ref/debar/default.htm.
2. The credentialing staff shall assure that the researcher is not DISQUALIFIED from prescribing investigational agents as evidenced by not being on the FDA Disqualified/Totally Restricted List located at http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm
3. The credentialing staff shall note if the investigator has an active ASSURANCE (located at http://www.fda.gov/ora/compliance_ref/bimo/asurlist.htm) or other RESTRICTION (located at http://www.fda.gov/ora/compliance_ref/bimo/restlist.htm) on file with the FDA concerning their use of investigational agents.

- 3.1. In the event there is an Assurance or Restriction, the credentialing approval letter shall dictate that they may not practice outside of the scope allowed by such Assurance/Restriction.
4. Documentation on the application form or other note to file indicating the above checks have been verified and the nature of any Assurance or Restriction.