



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

<b>Title: <u>ICH Guidelines for Safety Reporting</u></b>		<b>Version # 1</b>
<b>SOP Number: OCR-AE-003</b>	<b>Effective Date: August 2013</b>	<b>Page 1 of 1</b>

**PURPOSE:** Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related

**POLICIES:**

1. All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB/IEC.
2. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.
3. For reported deaths, the investigator should supply the sponsor and the IRB/IEC with any additional requested information (e.g., autopsy reports and terminal medical reports).