Nova Southeastern University
Standard Operating Procedure for GCP

Title: Policy on Preparation of Informed Consent Form		Version # 1
SOP Number: OCR-ICF-001	**Effective Date: August 2013**	**Page 1 of 2**

POLICY: The Principal Investigator may provide OCR with informed consent for assistance to ensure compliance with NSU IRB, federal and local law requirements.

PROCEDURE:

1 The sponsor or investigator prepares the Informed Consent (IC) according to the NSU IRB manual.

1.1 Investigator provides investigator's contact information, location, names and contact information of sub-investigators.

1.2 OCR reviews the IC.

1.3 OCR reviews the Clinical Trial Agreement (CTA) for subject injury reimbursement (SIR) and coverage cost provisions with the IC document to insure consistency between IC and CTA. Subject injury language must correspond exactly to the injury clause in clinical trial agreements

1.4 Confidentiality section is reviewed to ensure all agencies and persons who may have access to clinical research information (for example, IRB, sponsors, NSU personnel, FDA; and in the case of dental investigators practicing under teaching certificates, the American Dental Association).

1.5 NSU customized IC sent back to sponsor for approval

1.6 Sponsor approved draft of IC submitted to IRB with the Submission Form for Initial Review

2. IRB approves or recommends modifications

2.1 Modifications inserted and returned to sponsor for approval

2.2 Sponsor approved changes submitted for final approval by IRB

3. Please refer to the IRB Consent Form Checklist found on the NSU IRB website

References:

- 21 CFR50.23, 24, 25(a)(1-8), 25(b)(1–6), 27(b)(2)
- 45 CFR46.116(a)(1-8), 116(b)(1–6), 117(a), 117(b)(2), 117(c)
- ICH Harmonized Tripartite Guideline E6: Good Clinical Practice (http://www.ich.org/LOB/media/MEDIA482.pdf)
- FDA Information Sheets—The Consent Process http://www.fda.gov/oc/ohrt/irbs/informedconsent.html
- OHRP: Tips On Informed Consent (Revised 3/16/93) http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm
- OHRP: Obtaining And Documenting Informed Consent Of Subjects Who Do Not Speak English (November 9, 1995) http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm
- OHRP: Informed Consent--Legally Effective and Prospectively Obtained (August 12, 1993) http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc93-03.htm
- OHRP: "Exculpatory Language" in Informed Consent (November 15, 1996) http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm
- NSU IRB Manual http://www.nova.edu/irb/manual/forms/informedconsent_checklist.pdf