AO-703: Sub-Contracts

1.0 OBJECTIVES

1.1 This procedure describes the methods and policies for developing, negotiating, and finalizing sub-contracts for trials conducted at affiliates of Northwestern University (NU) and coordinated through the Clinical Research Office (CRO).

1.2 This procedure is intended to meet institutional and federal guidelines regarding contract negotiations.

2.0 RESPONSIBILITIES

2.1 This SOP applies to those members of the clinical research team involved in the processing of affiliate sub-contracts. This includes the following:

- Contract Administrator
- Administrative Assistant
- Quality Assurance Monitor

3.0 APPLICABLE REGULATIONS AND GUIDELINES

3.1 21 CFR 312.50 General responsibilities of Sponsors

3.2 Northwestern University Office of Sponsored Research Policies

3.3 Northwestern University Office of Sponsored Research OSR-1 Instructions

3.4 Northwestern University Office of Sponsored Research OSR eProposal User System Guide

4.0 REFERENCES TO OTHER APPLICABLE SOPs

4.1 A-SSU-115: SRC Protocol Review and Approval

4.2 AO-701: NU Participating Sites-Interaction Post-Activation

5.0 DEFINITIONS

5.1 **Clinical Trial Agreement (CTA):** A legally binding agreement that manages the relationship between the Sponsor who may be providing: Study Drug or Device, Financial Support, Proprietary Information; and Northwestern, who may be
providing: Data and/or Results, Intellectual Property, Publication, Input into Publication, Input into further Intellectual Property.

5.2 **Office of Sponsored Research (OSR):** The OSR facilitates research at Northwestern University by efficiently and effectively identifying funding sources, assisting in proposal development, reviewing and endorsing proposals, negotiating agreements, accepting and appropriating awards, interpreting guidelines and promoting compliance with sponsor and University policies.

5.3 **Scientific Review Committee (SRC):** The SRC is a part of the Lurie Cancer Center’s Clinical Protocol Scientific Review & Monitoring System (CPSRMS) and is an independent committee responsible for reviewing new clinical trials to ensure that they are scientifically sound. The SRC conducts a full scientific review of all cancer-relevant studies that have not received external peer review by a NIH-approved peer-review body.

5.4 **Sub-contract:** A subcontract represents any portion of the research project that is performed by another center.

6.0 **PROCEDURES**

6.1 When a new or revised protocol is approved by the Scientific Review Committee (see A-SSU-115: SRC Protocol Review and Approval) the Contracts Administrator (CA) will ensure that the primary Clinical Trial Agreement (CTA) includes appropriate language that allows sub-contracts to be executed between NU and an affiliate. The primary CTA must be fully executed before OSR can begin sub-contract negotiations with an affiliate.

6.2 In the prime CTA that NU negotiates with a sponsor, the sponsor typically allots a strict dollar amount per patient. Using this amount, the CA develops an appropriate sub-site budget. NU site management fees and NU’s Facilities & Administrative (F & A) rate will be removed from any sub-site budget. If the potential affiliate requires information on the study budget to assess whether or not they can participate and return the signed Letter of Invitation, the AA will relay this to the CA. The CA will provide budget information upon request.

6.3 The CA will obtain a signed OSR Form 6 (OSR-6) from the NU PI (see attachment 7.1). The CA will deliver the signed OSR-6 and the CRO-approved sub-site budget to OSR along with a copy of the NU IRB approved protocol.

6.4 After OSR confirms that the NU IRB has approved the protocol and that they have executed the prime CTA, they will then negotiate the sub-contract with the affiliate. When all required departments have approved the budget, negotiations are finalized, and both the affiliate and NU IRBs have approved the protocol, the sub-contract can be executed. At minimum, the NU Department Chair, the NU PI, the affiliate PI, and OSR must sign the sub-contract.

6.5 The CA will notify the Administrative Assistant (AA) and the QAMs that the sub-contract is executed. Upon full execution of the sub-contract, the AA will enter all
affiliate information into NOTIS and enter the date that the sub-contract was executed. The CA will communicate any relevant information regarding drug shipment or distribution to the investigational pharmacist.

6.6 The CA will file the sub-contract appropriately. The CA will initiate the process of extending the sub-contract with OSR as needed.

6.7 Delinquent Data and Affiliate Payment Procedures

6.7.1 Sub-contracts executed between affiliates and NU may include language that connects data submission to affiliate payment. QAMs and the Financial Operations team are responsible for communicating with each other regarding any delinquent participating site data submission when this clause is included. The procedures regarding such communications will be followed as they are described in AO-701: NU Participating Sites-Interaction Post-Activation and the DMC Participating Site Data Compliance Policy.

7.0 ATTACHMENTS

7.1 OSR-6