AO-705: ECOG-ACRIN Affiliate Clinical Communications

1.0 OBJECTIVES

1.1 This procedure describes the policies and procedures related to clinical communications with Northwestern University (NU) Eastern Cooperative Oncology Group (ECOG-ACRIN) affiliates.

1.2 This procedure is intended to comply with all federal regulations, ECOG-ACRIN guidelines, NU Institutional Review Board (IRB) guidelines and adhere to Good Clinical Practice (GCP).

2.0 RESPONSIBILITY

2.1 This SOP applies to the employees of the CRO involved in receiving, distributing, evaluating, and submitting clinical communications to and from ECOG-ACRIN affiliates. This may include:

- NU ECOG-ACRIN Principal Investigator (ECOG-ACRIN PI)
- Affiliate PI
- Affiliate Staff
- Associate Director of Clinical and Affiliate Operations
- Affiliate Site Coordinator
- Quality Control Manager

3.0 APPLICABLE REGULATIONS AND GUIDELINES

3.1 21 CFR 312.60 General responsibilities of investigators

3.2 21 CFR 312.62 Investigator recordkeeping and record retention

3.3 21 CFR 312.64 Investigator reports

3.4 May 9, 1997 International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline

3.5 ECOG-ACRIN Policy and Procedures Manual

4.0 REFERENCES TO OTHER APPLICABLE SOPs

5.0 DEFINITIONS
5.1 Northwestern Oncology Trial Information System (NOTIS): A web-enabled clinical trial management system that was developed to comprehensively capture data generated by cancer clinical trials.

6.0 PROCEDURES

6.1 Affiliate Membership and Membership Application Process

6.1.1 Affiliates interested in becoming a NU ECOG-ACRIN affiliate should become familiar with the membership application process detailed in the ECOG-ACRIN Policies and Procedures Manual.

6.1.2 Potential affiliates interested in NU ECOG-ACRIN affiliate membership should contact the Affiliate Site Coordinator (ASC) to begin the application process.

6.1.3 The ASC will act as the primary administrative point of contact for both the affiliate and ECOG-ACRIN Coordinating Center during the membership application process.

6.1.4 When NU is unfamiliar with a site applying for membership, the NU ECOG-ACRIN Principal Investigator (ECOG-ACRIN PI), CRO Administrative Director (AdD), and the CRO Associate Director of Clinical and Affiliate Operations (ADCAO) may schedule a teleconference to assess the affiliate’s interest. The team may then conduct a site evaluation visit or conduct a conference call in place of a site evaluation visit. The Quality Control Manager (QCM) will electronically forward all applicable implemented SOPs to potential affiliates.

6.1.5 If the ECOG-ACRIN PI approves a potential affiliate, he or she will send a formal, written letter of support to the affiliate, as is required as part of the ECOG-ACRIN membership application process. The ASC will facilitate this process.

6.2 ECOG-ACRIN Subject Registration and NOTIS Entry

6.2.1 Affiliates will register subjects for cooperative group studies per the process dictated by each protocol. If the ECOG affiliate uses the NU IRB as their IRB of record, the affiliate staff is then also responsible for entering subject registration information into NOTIS. These affiliates must complete NOTIS training before they may open an ECOG study through NU.

6.2.2 Once a subject is registered to protocol, the ECOG-ACRIN PI receives confirmation of affiliate subject registration via mail. The ECOG-ACRIN PI will forward this to the ASC. If the affiliate does not use the NU IRB as their IRB of record and has chosen not to use NOTIS as their clinical trial
management system, the ASC will enter the subject information into NOTIS.

6.2.3 When there is a change in subject survival status, an affiliate that uses the NU IRB as their IRB of record must promptly update the subject’s status in NOTIS. The ASC will check with all NU IRB affiliates at least annually (at the time of continuing review) to ensure that all subject statuses are up-to-date.

6.3 Regular Communications between NU and ECOG-ACRIN Affiliates

6.3.1 Affiliate sites are expected to promptly update the ASC regarding any changes in personnel or contact information for staff or faculty who work on cooperative group studies.

6.3.2 The CRO conducts teleconferences for all ECOG-ACRIN affiliates. The ASC will send all communications regarding the teleconferences. Affiliate staff will have the opportunity to suggest items for the agenda. Affiliate participation is mandatory.

6.3.3 The ADCAO will finalize the agenda for each teleconference and facilitate the call. Delinquency reports, common questions or issues regarding ECOG-ACRIN Policies and Procedures, and questions regarding high-accruing ECOG-ACRIN studies may be discussed. After the teleconference, the ADCAO will finalize meeting minutes and the ASC will distribute them to affiliate staff. The ASC will file both the agenda and the minutes in the appropriate places on the server.

6.4 Data Submission, Data Queries, and Data Delinquency

6.4.1 All affiliates will submit data according to the timelines dictated by each protocol. Unless otherwise indicated in a protocol, or individual institutional agreement, affiliates will submit all data directly to the cooperative group (not to the CRO). All pathology submissions and QARC data should be submitted directly to the ECOG-ACRIN Pathology Coordinating Office and QARC unless otherwise indicated by the protocol.

6.4.2 Data queries (ECOG-ACRIN sends Data Clarification Forms [DCFs]) are requests for clarification of data or requests for the submission of missing forms. Depending on the nature of the query, or the particular study, an affiliate DCF may be initially routed to the ECOG-ACRIN PI, AdD, or ADCAO. Any CRO employee that receives DCFs for affiliates will forward the request to the ASC. The ASC will forward all DCFs to the appropriate affiliate personnel.

6.4.3 Affiliate personnel that receive DCFs or other queries should respond to the cooperative group directly.
6.4.4 In order for the NU ECOG-ACRIN network to be considered in good standing, the network must have submitted ninety percent of all required data at the time ECOG-ACRIN generates quarterly delinquency reports. If the NU network has submitted less than ninety percent of data, accrual for the entire network will be suspended until outstanding data is submitted. The ECOG-ACRIN Coordinating Center performs “delinquency runs” on January 1st, April 1st, July 1st, and October 1st.

6.4.5 ECOG-ACRIN affiliates are responsible for timely data submission. ECOG-ACRIN affiliates are expected to monitor their own data compliance by regularly running Performance Monitoring Reports, eDCF reports, and Expectancy Reports via the ECOG-ACRIN Web Application Portal. The ASC will also regularly run these reports for each ECOG-ACRIN affiliate and will communicate with affiliates and the ADCAO regarding delinquent data as needed. Affiliates are expected to promptly respond to NU queries regarding delinquent data.

6.4.6 At the time of ECOG-ACRIN delinquency runs, the ASC may request that an affiliate submit particular data to either NU or to ECOG-ACRIN. Affiliates are expected to comply with all NU requests related to data delinquency runs.

6.4.7 If an ECOG-ACRIN affiliate fails to address data delinquencies, fails to respond to NU queries or ECOG-ACRIN DCFs, or if NU identifies any other areas of non-compliance, formal corrective action may be requested or formal disciplinary action will be taken. The ECOG-ACRIN PI will issue any formal requests for corrective action or any formal disciplinary action in collaboration with the ASC, AdD, and ADCAO.