

Clinical Research Organization

Title: **Study Activation Procedures**

Abbreviations

CRC	Clinical Research Coordinator
CTO	Clinical Trials Office
EDDO	Early Drug Development Office
IDS	Investigational Drug Service
MDG	Multidisciplinary Disease Group
OIC	Outpatient Infusion Center
PI	Principal Investigator
PSU	Protocol Support Unit
QIU	Quality Assurance and Process Improvement Unit
RNO	Regional Network Office

Process

Once a study is ready to be activated (i.e. open to accrual), the following steps will occur:

1. Activation Announcement (Local)
 - a. The lead CRC or Project Manager sends an Activation Announcement e-mail
 - b. The following people will be included on the e-mail: PI, Matt Huesser, Regulatory Coordinator, PSU Regulatory Manager, PSU Director, QIU Director, MDG committee members, RNO Sr. Director, EDDO Sr. Director, CTO Sr. Director, and other relevant study personnel like IDS and OIC if appropriate
 - c. The e-mail will be written using the approved Activation Announcement e-mail template.
 - d. The completed Clinical Trial Announcement form will be attached to the Activation Announcement e-mail.
2. JeffTrial Protocol Status
 - a. Upon receipt of the Activation Announcement e-mail, the Regulatory Coordinator will update the protocol status in JeffTrial to OPEN TO ACCRUAL with the date of the announcement e-mail.
 - b. This will occur ASAP (within 24 hours).
3. Activation Announcement (SKCC-Wide)
 - a. Matt Huesser will receive the Activation Announcement e-mail and include the Clinical Trial Announcement in the next "SKCC Week in (P)Review" e-mail.