

STROKENET TRIAL START UP PHASE — SITE COMMUNICATION v6.3.2022

Task	Primary Responsibility of Communication to Site	Copied in Email <i>*allow to review prior to send out</i>	Attachments	Deadline for Sites	Follow Up Plan & Comments
PRIOR TO RECEIPT OF NOTICE OF AWARD (NoA) FROM NINDS					
Site selection survey to sites	Drafted by Prime* PI+PM, with NCC PM Programmed/sent by NDMC to RCC PI+PM RCC PM sends to sites (incl satellites) to complete <i>*Prime=Prime refers to Trial Grant Awardee</i>	*NCC MPI (Joe/Pooja) *NCC Admin Co-Director (Jamey/Laura) Prime PI+PM NCC PM	Trial synopsis Draft Startup and Per Pt Budget, <i>if available</i>	3 weeks	Lack of response=not interested <i>Prime PI uses these data to select sites</i>
Site commitment letter to sites	Drafted/sent by NCC PM To Site PI+PM Informs site	*PRIME PI+PM NCC PI RCC PI+PM	Trial synopsis Startup and Per Pt Budget, <i>if requested</i>	N/A	N/A <i>Communication includes:</i> <ul style="list-style-type: none"> • <i>Timeline for next steps (upcoming CTA & cIRB packets)</i> • <i>Need for final local PI and coordinator names</i> • <i>Request for immediate notification if no longer participating</i>
DURING PERIOD BETWEEN NOA RELEASE AND NCC SUBCONTRACT EXECUTION (USUALLY 4-6 WEEK PERIOD)					
<p>(1) Prime PM or Research Office sends Notice of Award (NoA) to NCC upon receipt</p> <p>(2) NCC Contracting makes Clinical Trial Agreement (CTA) template and sends to UC general counsel for approval and signature delegation</p> <p>(3) Prime Institution sends subaward to NCC; NCC reviews financial terms, contracting reviews legal terms; signed by legal & Sponsored Research Services at UC</p> <p>(4) UC sets up accounting (5-7 days)</p>					
AFTER NCC SUBCONTRACT IS EXECUTED					
“CTA (Clinical Trial Agreement) Packet” <i>Released within two weeks of NCC subcontract execution</i>	Sent by NCC Contracting For completion by site	Site PM+PI Site Admin contact NCC PM Prime PI+PM RCC PI+PM	CTA cIRB approval letter Notice for single IRB Fully executed Reliance Agreement (RA) or RA Amendment – UC IRB only CTA contains the payment schedule and SOW (and/or links) via Attachment 5	4 weeks	Follow up for each packet: <ul style="list-style-type: none"> • Four weeks from mailing: If no communication from site, NCC PM will email Site PI+ coordinator (cc contracting) to confirm receipt and that work has started at site • Six weeks: If CTA/cIRB not returned/submitted, NCC PM asks Prime PI to talk to (email/call) Site PI to inquire about progress at the site. • Two months: If CTA/cIRB not returned/submitted, NCC Regulatory/Contracting will email sites • Three months: If CTA/cIRB not returned/submitted, NCC PM will email/contact site for timeline to complete these tasks and update Prime PI • Final notice: If CTA/cIRB not returned/submitted by communicated delivery date and has not communicated a new delivery date, NCC PM will give final notice (typically, two weeks) • Final decision: If CTA/cIRB not returned/submitted by planned deadline, Prime PI will then decide to allow the site extra time or, drop the site. <p><i>Notes:</i></p> <ul style="list-style-type: none"> • <i>NCC PM should cc corresponding contracting/regulatory staff, and vice versa, in addition to cc'ing the others in column 3</i> • <i>Contract execution is performed by UC Sponsored Research Services (SRS)</i>
“Regulatory Packet” <i>Released when final protocol and ICF are IRB approved and coordinated with CTA distribution</i>	UC IRB: Sent by NCC Regulatory ADVARRA: Sent by NCC PM with Advarra input. Site submits application to CIRBI For completion by site	Site PI+PM Site Admin contact Prime PI+PM RCC PI+PM	UC IRB: Local Site Context form (to be signed by the Local IRB) ICD template(s) ADVARRA: Informed Consent template and other trial regulatory documents Reliance agreement (if not in place) IF APPLICABLE: 1572 form if IND; Investigator form if IDE	4 weeks	
Advarra Reliance Agreement (RA)	NCC PM	Advarra IRB NCC Contracting			Advarra IRB will work with site to get RA executed