NUCATS Center for Clinical Research (CCR)
Regulatory Coordinator & Study Coordinator Responsibilities

The NUCATS CCR Regulatory Coordinator Team's responsibilities include IRB Submission to internal and external IRBs, assisting with sponsor investigator FDA submissions, regulatory binder creation, maintenance, and monitor visit support. The regulatory team works closely with the study teams to ensure that clinical trial research studies and documentation are properly maintained during the pre-IRB, IRB, and post-IRB submission phase.

IRB Submissions and Document Maintenance:

The following list highlights IRB submissions and modification tasks list:

- Preparation of study documents for initial IRB submission, modification, and annual submission responsibility
- Protocol amendments and modifications to study documents including but not limited to informed consent form, Investigators Brochure, recruitment materials, personnel changes, continuing review/study close-out, annual study, and maintenance reports
- FDA/regulatory document preparation (1572, FDFs, signature pages, etc.)
- Regulatory binder creation
- Interface with study team, sponsor, CRO (if applicable), IRB of record, and FDA (if applicable) Clinicaltrials.gov support
- Regulatory coordinators work with the study teams, PI, or Sub-I to ensure that any document that needs a signature are obtained in a timely manner. The file will be saved and/or sent back to the sponsor for proper filing.
- Sponsor required documentation and training log paired with amended modifications

IRB Submissions and document maintenance/study updates are submitted internally to Northwestern University IRB, and external to central IRBs such as WCG, Advarra, etc. The submission, modification, and closure process will be led by the regulatory coordinator once all documents have been received by the sponsor or study team. Consent form edits will be made by the regulatory coordinator once informed of changes. The edits will be reviewed by the study team and the sponsor before IRB submission for approval. Generally, if edits are requested by the sponsor due to an amendment from the sponsor's side, the sponsor will forward requested red lined items to the study team and/or regulatory coordinator. The study team should **always** forward important correspondence to the regulatory coordinator, in the event that it may not have been received by the regulatory team. Once confirmed, the regulatory coordinator will modify forms and prepare to send back edits for submission approval from the sponsor. Once sponsor approval is received, the documentation will be submitted to the respective IRB of record for review and approval.

The general steps for processing an IRB approval at the internal and external level are listed below:

1. Receive email approval notice from the NU IRB or external IRB system.
2. Retrieve the approval letter and documents from the NU or external IRB portal.

If receiving an approval from the external IRB, the form will need to be processed by NU IRB for acknowledgement.

3. Save the approval letter and documents to the Shared drive in the appropriate subfolders within the study folder using the appropriate file-naming convention.
4. Forward the approval letter and documents to the study team and sponsor contacts, as needed.
5. File the approval letter and documents in the regulatory binders (printed for physical binders/saved in E-Reg/upload and file in Complion).

Complion, E-Regulatory, and Physical Binders:

E-Regulatory binders or Complion regulatory binders are created for new studies while physical (paper) binders which are maintained on site are for older studies. As of 9/1/2021, NU FSM policy states that all studies that are approved by the NU IRB and are FDA-regulated and/or multi-site will utilize Complion for electronic regulatory binders. Please refer to the Complion resource page and policy.

All final/approved documents of the study will have to be filed in the Complion regulatory binder. The Complion system automatically populates regulatory binders with study team members' CVs, medical/professional licenses, and CITI training. Sponsors/monitors can be granted access to the Complion binder prior to a monitor visit for the duration of their visit. At the end of the study, the Complion binder will shift to an "inactive state" while documents uploaded will remain in the binder. If study teams would like documents provided to them for record keeping they can receive a printed out final version of the binder or USB drive with contents of the binder saved for their records.

E-Regulatory binders are comprised of folders, containing final/approved documents which model a physical regulatory binder. Sponsor correspondence and study documents are saved in the E-Reg and the other study folders. The regulatory coordinators ensure that the E-Reg folders are up to date on a rolling basis. Any time new study correspondence is received, it will be filed accordingly by the regulatory coordinator. When notified of an upcoming monitoring visit, the regulatory folders will be checked to make sure that files are saved in the appropriate place, and files which may have expired are updated. This includes but is not limited to: filing all IRB approvals, updating IRB rosters to most current, logs are accurately complete, confirming that study team member CITI training/CVs/licenses are all present and up to date, etc. Regulatory staff upload the E-Reg folder to OneDrive and provide monitor access to that folder for review and to note if any changes need to be made for the review period. At the end of the study when it closes, the regulatory coordinator will provide the study team with a final access to the e-Reg documentation by SharePoint link, USB drive of files or final printed version of all documentation from the e-Reg.

For physical regulatory binder maintenance, the regulatory coordinator is responsible for printing and filing documents in them, as well as transport of binders to and from monitor visits, which are usually hosted at the study team's department. Document filing is completed on a rolling basis once received from the sponsor contact or from the study coordinator. Binder location and maintenance of the files included will be communicated amongst the study team and regulatory coordinator throughout the duration of the study.

NOTE: If eReg/Complion and physical binders are being utilized, there will **not** be more than one regulatory binder. A physical binder will serve as a point of reference to the eReg binder during monitoring visits and audits, however, the eReg will be updated regularly.

Monitoring Visits:

The study team and regulatory coordinator will correspond with the sponsor and monitor to plan the on-site/remote visit, four (4) weeks in advance of the preferred visit date. The four-week notice is optimal for thorough review and preparation, and with consideration of study volume coverage of regulatory support. Due to coverage demands, the regulatory coordinator ***is not*** required to be present in-person throughout the entire time the sponsor monitor is on site. The study team and monitor can schedule with the regulatory coordinator, as needed, for 30 min-1 hour to meet to review regulatory updates or requests through virtual meetings. If the regulatory coordinator and monitor are unable to meet the day of a visit, a follow up visit can be arranged virtually. There may be circumstances which arise where a sponsor will need to return to site more frequently, which does not allow for 4-week advanced notice. If an urgency arises, the monitor visit needs to be communicated by the study team and monitor immediately to the regulatory coordinator due to time constraints.

Study Specific Document or Key Personnel Training:

Training documentation will be confirmed by the study sponsor, upkept by regulatory coordinator, and collected by the study team when needed. At site initiation the sponsor will conduct protocol training, along with other essential training required by the sponsor for their records. Additional trainings that may occur throughout duration of the study might include updated protocol documents, investigator brochure or pharmacy manuals etc., these trainings will be documented on training logs provided by the study sponsor. Wet ink or electronic signature will be obtained by the study team and filed by the regulatory coordinator. The study team, sponsor and assigned regulatory coordinator will be aligned regarding proper documentation. All personnel related to the study will communicate frequently to

determine when new trainings are required, who needs to be trained, duration of the training period and the appropriate filing mechanism to meet regulatory requirements.

Study Team Meetings and Communications:
The study team should inform the regulatory coordinator of any new study updates, study personnel changes, regulatory documentation upkeep and study team meetings through email or to attend scheduled in person/virtual meetings. Regulatory coordinators do not need to be present during all study team meetings, however, regulatory coordinators should be informed of upcoming meetings to learn of new pertinent study information.

Sponsor Communication and Correspondence:
Newsletters and email updates should always be sent to the regulatory coordinator. Most news blasts and study updates which come from the sponsor are only sent to the clinical research coordinator and the regulatory coordinator is not listed on the sponsor communication listserv. To ensure that the regulatory team is properly notified of any study modifications, updates, closures, etc., the clinical research coordinator needs to forward all sponsor correspondence to the assigned regulatory coordinator so that regulatory can confirm receipt and file appropriately for future reference.

Delegation of Authority and Document Signatures:
The NU IRB has defined standards on study engagement (HRP-311 SOP) and in alignment, CCR Regulatory personnel do not interact with research participants, have access to identifiable research participant data, nor considered engaged in the research study. Accordingly, only investigators and staff who meet the criteria for engagement should be listed on the DOA log for a trial. CCR Regulatory staff are not responsible for obtaining signatures, including both electronic and/or wet ink. The assigned study team is responsible for obtaining all signatures, and regulatory personnel will oversee those signatures are appropriately completed.

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Regulatory Coordinator & Study Coordinator Responsibilities

Regulatory Coordinator Responsibilities	Study Coordinator Responsibilities
IRB Submissions – New Project Submissions	
• Process regulatory packet • Prepare regulatory documents for signature • Draft informed consent form(s) • Complete IRB submission • Respond to IRB if clarifications are requested • Prepare regulatory binders for SIV (includes combining sponsor binders with reg binders)	• Forward regulatory packet to regulatory coordinator (including all necessary study documents and regulatory documents) • Provide PI's and Sub-Is' medical licenses and CVs • Review drafted consent form(s) prior to submission (if applicable) • Obtain signatures on regulatory documents • Assist regulatory coordinator in responding to IRB's clarification request (if applicable) • Provide lab reference ranges (if applicable)
IRB Submissions – Continuing Review	
• Obtain enrollment information from sponsor and study coordinator • Complete IRB submission • Respond to IRB if clarifications are requested • Notify sponsor and study team when approval is received • Print and file IRB approval documents in regulatory binders	• Provide enrollment information to regulatory coordinator • Assist regulatory coordinator in responding to IRB's clarification request (if applicable)
IRB Submissions - Modifications	
• Revise any study document affected by proposed modification (i.e., consent form, recruitment material, etc.) • Complete IRB submission • Respond to IRB if clarifications are requested • Revise regulatory documents (if applicable) • Notify sponsor and study team when approval is received • Print and file IRB approval documents in regulatory binders • Check with the study team regarding documentation of signatures for amendment training as required by the sponsor	• For Investigator-Initiated studies: provide protocol in tracked changes with proposed modification (if applicable) • Forward any sponsor correspondence/documents about sponsor-initiated modifications • Review any revised study document affected by proposed modification • Obtain signatures on regulatory documents (if applicable) • Assist regulatory coordinator in responding to IRB's clarification request (if applicable) • Document modification training by study team if required by the sponsor and forward to the regulatory coordinator

Regulatory Coordinator Responsibilities	Study Coordinator Responsibilities
IRB Submissions – Reportable New Information (RNIs)	
• Complete IRB submission • Respond to IRB if clarifications are requested • Notify sponsor and study team when acknowledgement is received • Print and file IRB approval documents	• Notify sponsor and regulatory coordinator when any type of adverse event or unexpected problem/risk (i.e., AE/SAE/UPIRSO) needs to be submitted to the IRB • Provide details of event to regulatory coordinator • Complete adverse event form provided by sponsor and obtain PI's signature (if needed) • Assist regulatory coordinator in responding to IRB's clarification request (if applicable)
Monitor Visits – Site Initiation Visit (SIV), Initial Monitoring Visit (IMV), etc.	
• Review/prepare regulatory binders for visit • Review monitor confirmation letter to prepare to address any open regulatory action items • Be available for any regulatory questions during the visit – and will address any requests stemming from monitor visit • Retrieve regulatory documents • Assist study coordinator with point-by-point response to regulatory action items in monitor follow-up letter	• Schedule monitor visit with sponsor and regulatory coordinator with 4 weeks in advance notice • Reserve conference room for visit • Notify regulatory coordinator of final visit date, time, and location • Forward monitor confirmation letter to regulatory coordinator • Review monitor confirmation letter to prepare to address any open subject-specific/study data action items • Review/prepare subject binders for visit • Escort monitor to various meetings (pharmacy, clinic, etc.) • Assist monitor with copies • Retrieve subject documents • Forward monitor follow-up letter to regulatory coordinator or ensure regulatory is an email recipient • Draft point-by-point response to monitor follow-up letter with assistance on regulatory action items from regulatory coordinator
Miscellaneous Day-to Day Operations	
• Attend research meetings • Correspond with sponsor and study team to maintain miscellaneous study upkeep within regulatory binder • All regulatory-related tasks which include obtaining the necessary documents needed for filing (including wet signatures from PI/study team).	• Attend research meetings • Correspond with regulatory coordinator to maintain miscellaneous study upkeep of study procedures • All subject-related tasks • Obtain necessary signatures on documents for filing (including wet ink signatures).

Regulatory Coordinator Responsibilities	Study Coordinator Responsibilities
Complion Binder Management	
• View document as PDF • View source file document • Send and provide e-signature • Initial index of document type and descriptors • Re-index of document type and descriptors • Download source files as PDF with and without signature • Send documents for action • View and add unfiled documents • View the status of documents and history of files • Ability to upload files • Ability to edit binder details • Manage external user access • Manage tasks in binder • Manage the delegation of authority log • Access reports	• View document as PDF • View source file document • Download source files as PDF with and without signature • Send documents for action • View and add unfiled documents • View the status of documents and history of files • Ability to upload files • Manage the delegation of authority log • Sponsor role– indicates that a training log needs to be updated based on new amendments. • Sponsor role – indicates that a training log needs to be updated based on new amendments
FDA Submissions – IND & IDE Annual Reports	
• Assist PI and study team with FDA annual report submission • Review cover letter and application document for submission • Prepare regulatory documents for signature • Prepare submission for E-submission or mailing if required (make copies of submission, pack in envelope/box, fill out shipping label) • Correspondence with FDA and study team	• Provide regulatory coordinator with annual review information (enrollment #s, adverse events, unanticipated problems, etc.) • Draft cover letter and application document and send to regulatory coordinator for review • Obtain signatures on regulatory documents • Provide regulatory coordinator with chart string and FedEx account number for submission shipping and billing • Assist regulatory coordinator in responding to FDA's clarification request (if applicable)