MARY CROWLEY CANCER RESEARCH
HOPE LIVES HERE™

12222 Merit Drive, Suite 1500
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Administrative Processes

Staff/ Communication of Trial Information to Sites	
Project Manager	(1) Full time Project Manager is assigned to each study. They are the main point of contact and are responsible for all study-related issues, clinical and administrative. A manager or another PM trained to the study provides backup coverage.
Regulatory Specialist	(1) Full time Regulatory Specialist is assigned to each study. They are responsible for the regulatory binder, ICF creation/ maintenance, and all regulatory submissions. The Project Manager provides backup coverage.

Monitoring	
Description of Monitoring Facilities	The monitoring suite has a copier and 12 cubes, each with their own phone line and desktop monitor limited to access to the EMR. Visitors will need to bring a personal laptop to connect to the Wi-Fi for access to the EDC.
Monitor's access to the EMR	All monitors and co-monitors will be provided with their own username and password for read only access to only the patients that are on their trial. Monitor/CRA access is only granted the week of the scheduled visit, and audit trails can be provided to show records accessed by monitor. Training is not required, but a verbal training can be provided by MCCR staff if assistance is necessary.
Scheduling a Monitoring Visit	Monitoring hours are from 8am-5pm (M-F). All visits should be scheduled through the Research Operations Coordinator (they will coordinate PI meeting, lab, pharmacy, and data review). Monitor/CRA visits may be scheduled for up to 3 days for 2 monitors. Anything outside of those parameters requires prior approval. Co-monitors are encouraged as long as space allows. At least 3 weeks advanced notice of visit dates and those attending is necessary.

Regulatory Binders	
Regulatory Documents	The MCCR regulatory binders are kept electronically in Florence (Part 11 compliant).

FDA Audits	
MCCR FDA audits	The Mary Crowley Cancer Research site has been audited by the regulatory authorities 4 times – in 1996, 1998, 2000, & 2006. Form 483s were issued to the facility in 1996 & 1998 for minor issues, and SOPs were updated to provide corrective action. Form 483s are available upon request. The site is listed as Texas Oncology PA, which MCCR use to complete research under.
MCMRC IRB FDA audits	The Mary Crowley Medical Research Center IRB was audited by the regulatory authorities in 2008, 2014, and 2020. A Form 483 was issued to the board in 2014 for a minor issue, and a thorough corrective action plan was provided and accepted by the FDA.

Disaster Recovery Plan	
Protection	Most regulatory documents and medical charts are electronically stored and backed up to multiple servers. Any remaining printed documents are protected by sprinkler and extinguishing systems.
Recovery	If any paper documents are devastated, Mary Crowley will take steps to recreate the hard copy of the devastated files by working with the Sponsor, CRO, IRB, IBC and any other entities deemed necessary.

Development Timelines	
Overall	The site can typically open studies within 10 weeks, but can be as low as 6 weeks with Sponsor/CRO timeline commitment discussions up front.
Regulatory Review	See the "Additional Review Committees" section below to determine impact on development timelines

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Development Timelines	
SIV Dates	SIV will be set about 1-2 weeks post expected last IRB approval release date (either MCMRC IRB or North Texas depending on requirements). The SIV date is set at site selection to establish tight timelines in getting activated. This provides a goal date for all teams involved to ensure activation in a timely manner.
FDA and IRB review in parallel	This site has a process in place to review a study in parallel with FDA review to help expedite study's timelines. While FDA changes may not be required, it is understood that comments could come back that would require an amendment. If this is the case, MCCR has processes in place to help mitigate any lost time, but the site must be compensated for the rapid work in addition to the typical start-up and amendment work. To ensure this, the site will need to have approval from Sponsor or Authorized Signatory regarding the additional fees via the FDA/IRB Parallel Review LOA. This is a requirement for the site to start working on this study.
Just In Time	This site has the capabilities to open a JIT trial. NOTE: JIT trials identify the patient for a trial prior to developing the study. These can be opened in 2 weeks from date of site selection. More information can be provided upon request.

Contract/Budget	
Development Timelines	Contract and Budget can be started with only a draft protocol and IB, but will be prioritized after studies that have provided all documents. Contract and Budget are conducted in parallel with all study start up processes (including IRB review and approval), but the goal is to have this in place by SIV. Timelines vary depending on responsiveness of the sponsor/CRO, but averages 10 weeks. If utilization of a previously negotiated master contract is allowed then it takes less than 8 weeks.
Required Language	Mutual confidentiality and Sponsor indemnification are a few of the required sections, but language can be negotiated.
Number of Contracts	There is only 1 contract that will need to be negotiated between the institution and the Sponsor. If the clinical trial agreement is between the institution and a CRO there will be an additional contract needed if the CRO is not able to bind the sponsor to the agreement. In that case, a standard Letter of Indemnification will be needed. Institution will hold all other contracts necessary for running the trial.
Signatures	There is a quick signature process, with multiple designees (CEO, PI or other designees) that can be available to sign on behalf of the institution. The site does not require wet ink signatures. However, if wet ink signatures are requested by the sponsor, MCCR can send this as long as a shipping label is provided.

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Review Committees

Mary Crowley Scientific Review Committee	
Necessity	Required for all studies.
Qualifications	The Executive Medical Director, Principal Investigator, Sub-Investigators, and key clinic staff will attend.
Impact on Development Timelines	From submission of documents to SRC approval released, this process is expected to take 1 week.

Mary Crowley Medical Research Center IRB	
Necessity	Required for all studies
Full Name & Address	Mary Crowley Medical Research Center Institutional Review Board 12222 Merit Drive, Suite 1500A, Dallas, TX 75251
Contact	The sponsor cannot directly contact the IRB. All communication should be directed through the site staff.
Qualifications	None of the investigators are members of this board. This is a local IRB and meets all FDA requirements. FDA registration numbers: IRB00005586 and IRB00004691.
FDA and IRB review in parallel	The MCMRC IRB does allow for submission and meetings to occur in parallel with the 30 day review period for new INDs. However, approval will not be released until the review period is complete.
Expedited Research	Research found to involve no more than minimal risk and according to 21 CFR 56.110 can be reviewed expeditiously.
Impact on Development Timelines	Meetings are weekly aside from holidays. One meeting per month is reserved for continuing reviews (no initial protocols reviewed). From receipt of documents/site selection to IRB approval, this process is expected to take a total of 8 weeks (6 weeks prior to IRB meeting and 10 calendar days post IRB meeting). This review can be done in parallel with other development tasks (Budget, Contract negotiations, etc.)

Institutional Biosafety Committee	
Necessity	Not required for all studies. Only required for investigational products involving recombinant deoxyribonucleic acid (DNA) or human gene transfer. The first IRB to review this drug is responsible for determining if IBC will need to review the trial.
Qualifications	This is a central IBC and is a division of Western Institutional Review Board (WIRB). None of the investigators are members of this board.
Required Documents	Protocol, Investigator Brochure, Pharmacy Manual, and ICF.
Impact on Development Timelines	If this is required (see Necessities above), then it is not expected to add any time to the development timeline. This review can be done in parallel with other development tasks (MCMRC IRB Submission, Budget, Contract negotiations, etc.)

North Texas Med City IRB	
Necessity	Not required for all studies
Full Name & Address	North Texas Institutional Review Board at Medical City Dallas 12200 Park Central Drive, One Forest Medical Plaza, Suite 500, Dallas, Texas 75251
Qualifications	This is a local IRB and meets all FDA and OHRP requirements. Dr. James Strauss (an investigator) is a member of this board. Federal Wide Assurance #:FWA00000220. FDA registration number: IRB00000852
Required Documents	The IRB will require approval from the Mary Crowley Medical Research Center IRB and a *Study May Proceed Letter* from the FDA for initial submission.
Impact on Development Timelines	If this is required (see Necessities above), then it can add a total of 2-4 weeks depending on timing of submission. This review must be done sequentially, after receiving approval from the Mary Crowley Medical Research Center IRB.