MARY CROWLEY CANCER RESEARCH
HOPE LIVES HERE™

12222 Merit Drive, Suite 1500
Dallas, Texas 75251

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Administrative Processes

Staff/ Communication of Trial Information to Sites	
Study Staff	The dedicated (full-time) study Central Research Team includes: • 1 Project Manager: Main Point of Contact. Responsible for all study-related issues, clinical and administrative. (Manager or another PM trained to the study provides backup coverage) • 1 Regulatory specialist: Responsible for the regulatory binder, ICF creation/ maintenance, and all regulatory submissions. (Project Manager or Manager of Project Managers provides backup coverage) • 1 primary Contract team member and 1 primary Budget team member (see contact sheet). In addition to central research staff, the clinic location will also have research staff.
Protocol Specific Training	If additional in-person training is required for the updates, management staff will conduct accordingly.

Monitoring	
Description of Monitoring Facilities	Our central location monitoring suite has a copier and 12 cubes, each with their own phone line and desktop monitor limited to access to the EMR. Monitors will need to bring their own laptop to connect to our 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 the patients that are on their trial.
Scheduling a Monitoring Visit	Monitoring hours are from 8am-5pm (M-F). All visits should be scheduled through the Project Manager (they will coordinate PI meeting, lab, pharmacy, and data review). Monitor 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. We ask for at least 3 weeks advanced notice of visit dates and those attending.

Regulatory Binders	
Regulatory Documents	Our regulatory binders are kept electronically in Complion (Part 11 compliant).

FDA Audits	
MCCR FDA audits	Our 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. Form 483 and follow-up responses are all available upon request. The site is listed as Texas Oncology PA, which Mary Crowley use to complete research under.
MCMRC IRB FDA audits	Our IRB was audited by the regulatory authorities in 2008 and 2014. 483 was given for minor issue.

Disaster Recovery Plan	
Protection	Most regulatory documents and medical charts are electronically stored and backed up to multiple servers. The Central building is 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	Our site can typically open studies within 10 weeks, 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). We set our SIV date at site selection to establish tight timelines in getting our site activated. This provides a goal date for our team, as well as yours, to ensure we open in a timely manner.
Just In Time	Our site has the capabilities to open a JIT trial. NOTE: JIT trials identify the patient for a trial prior to developing the study at our site. 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 to our site. Contract and Budget are conducted in parallel with all study start up processes (including IRB review and approval), but our goal is to have this in place by SIV. Timelines vary depending on responsiveness of the sponsor/CRO, but averages 10 weeks. If we have a master contract in place with the sponsor/CRO 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. A letter of Indemnification (LOI) by the study sponsor is often required. Sponsor and CRO will negotiate 1 contract for each study (i.e no additional PI, vendor, or site specific contracts).
Signatures	We have a quick signature process, with multiple designees (CEO, PI or other designees) that can be available to sign on behalf of the institution. We do not require wet ink signatures.

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Additional Review Committees

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

Mary Crowley Medical Research Center IRB	
Full Name & Address	Mary Crowley Medical Research Center (Mary Crowley) dba Mary Crowley Cancer Research 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 our investigators are members of this board. This is a local IRB and meets all FDA requirements.
FDA Submission	Our 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.
Necessity	Required for all studies
Impact on Development Timelines	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 our other development tasks (Budget, Contract negotiations, etc.)

Institutional Biosafety Committee	
Qualifications	This is a central IBC and is a division of Western Institutional Review Board (WIRB). None of our investigators are members of this board.
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.
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 our other development tasks (MCMRC IRB Submission, Budget, Contract negotiations, etc.)

North Texas Med City IRB	
Full Name & Address	North Texas Med City IRB #1 7777 Forest Lane, Dallas, Texas 75230
Qualifications	Federal Wide Assurance #:FWA00000220. This is a local IRB and meets all FDA and OHRP requirements. Dr. James Strauss (an investigator) is a member of this board.
Necessity	Not required for all studies.
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.