MARY CROWLEY CANCER RESEARCH
HOPE LIVES HERE™

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Central Location 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.

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.
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). There is no limit to the number of days a monitor may book, but understand that near the holidays and during the summer, the 12 cubes can fill up fast. Co-monitors are encouraged as long as space allows. We ask for at least 3 weeks advanced notice of visit dates and those attending.
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.

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

Data Entry	
Experience	Our site has experience with RAVE, Inform, Oracle, Data Labs, iMedNet, Tempo and many others, including custom built EDCs.

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 used 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.

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Development Timelines	
Regulatory Review	See the "Additional Review Committees" section below to determine impact on 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.

Contract/Budget	
Development Timelines	Contract and Budget can both be 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.
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	
Study Requirements	All studies conducted at MCCR must be approved prior to starting development of the study.
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.

Mary Crowley Medical Research Center IRB	
Study Requirements	All Studies conducted at Mary Crowley must be approved prior to enrolling at our site.
Qualifications	This is a local IRB and meets all FDA and OHRP requirements. None of our investigators are members of this board.
Impact on Development Timelines	This process is expected to take a total of 8 weeks (6 weeks prior to IRB meeting and 10 calendar days post IRB meeting)
Contact	The Sponsor cannot directly contact the IRB. All communication should be directed through the site staff.
Expedited Research	Research found to involve no more than minimal risk and according to 45 CFR 46.110 and 21 CFR 56.110 can be reviewed expeditiously.

North Texas IRB	
Qualifications	This is a local IRB and meets all FDA and OHRP requirements. Please note that Dr. James Strauss (an investigator) is a member of this board.
Impact on Development Timelines	If this is required (see study requirements above as not all studies require this review), then it can add 2-4 weeks depending on timing of meeting.

Institutional Biosafety Committee	
Study Requirements	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 our investigators are members of this board.
Impact on Development Timelines	If this is required (see study requirements above as not all studies require this review), and this is the first IRB to review this drug, then it will add about 4 weeks to development timeline. If another IRB has already reviewed this drug, then this meeting can occur in parallel with the Mary Crowley Medical Research IRB review, and no time will be added to development timeline.