MARY CROWLEY CANCER RESEARCH

# Contact Sheet

| Name and Address of Facility where Clinical Investigation to be Conducted (Same as Box 1 & 3 of 1572) | | |
|---|---|---|
| Mary Crowley Cancer Research | 7777 Forest Lane, Building C, Suite 707, Dallas, Texas USA 75230 | FEI#: 3000206628 |

| Investigators (all individuals listed below will be on the 1572) | | | | | |
|---|---|---|---|---|---|
| 1 | Minal Barve, MD | | Oncology/ Hematology | ML#K9724 | NPI: 1245277698 |
| | Contact information for PI: | P:(972) 566-3000 | F: (972) 566-3099 | MBarve@MaryCrowley.org | |
| 2 | Douglas Orr, MD | | Oncology/ Hematology | ML#H7202 | NPI: 1194767061 |
| 3 | Reva Schneider, MD | | Oncology | ML#N3295 | NPI: 1487864864 |
| 4 | Racha Halawi, MD | | Oncology/ Hematology | ML#R2863 | NPI: 1841587235 |
| 5 | Shiela Haffar, MD | | Oncology | ML#M1737 | NPI: 1720010507 |
| 6 | Jairo Olivares, MD | | Oncology/ Hematology | ML#J9250 | NPI: 1770520165 |
| 7 | Leah Plato PA-C, MPH, CCRP | | Physician Assistant | ML#PA05945 | NPI: 1013161652 |
| 8 | Ntombizodwa Sayi MSN, RN, AGPCNP-BC | | Nurse Practitioner | ML#AP136246 | NPI: 1134621683 |

| Clinical Trial Manager | | | |
|---|---|---|---|
| Main Contact for all Issues | TBD closer to IRB date | | |

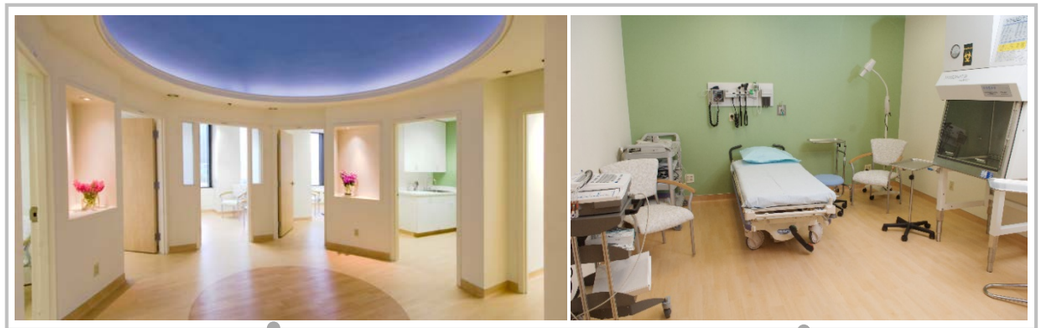
| Mary Crowley Cancer Medical City Dallas Clinic | | | |
|---|---|---|---|
| Name and Pharmacist Contact | | Mary Crowley Cancer Research Investigational Drug Repository | |
| Robert Nunan, MS, PharmD, BCOP | | P:(972) 566-3076 | RNunan@MaryCrowley.Org |
| *Address for drugs (physical & shipping)* | | 7777 Forest Lane, Suite C-707, Dallas, Texas 75230 | |
| Lab Kits and Clinic Logisitcs | TBD closer to IRB date | | |
| *Address for kits/clinical supplies (physical & shipping)* | | 7777 Forest Lane, Suite C-707, Dallas, Texas 75230 | |
| Enrollment/ Screening | TBD closer to IRB date | | |
| On Study patient updates | TBD closer to IRB date | | |

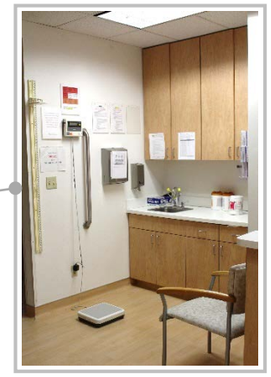
| Contract & Budget Information | ***DO NOT SHIP DRUG OR LAB SUPPLIES TO THIS LOCATION*** | | | |
|---|---|---|---|---|
| Contract / CDA Contact | Alex Duenas | P:(214) 505-4254 | ADuenas@MaryCrowley.org | |
| Budget Contact | TBD closer to IRB date | | | |
| Payee Contact | Danielle Sala | P:(214) 658-1970 | AR@MaryCrowley.org | |
| *Legal Institution Name:* | Mary Crowley Cancer Research | | *Tax ID Number:* | 75-2727375 |
| *Institution Payment Address:* | 12222 Merit Drive, Suite 1500, Dallas, Texas 75251 | | | |
| *Bank:* | (name) | (address) | | |
| | *Account Number:* | | *ABA Number:* | |

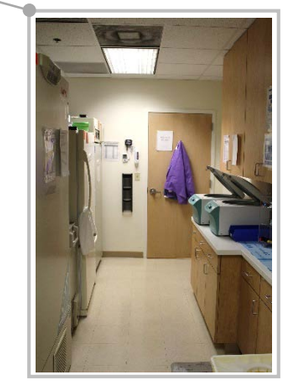
| Regulatory | ***DO NOT SHIP DRUG OR LAB SUPPLIES TO THIS LOCATION*** | | |
|---|---|---|---|
| Regulatory Specialist | TBD closer to IRB date | | |
| *Regulatory Doc Shipment (send electronically, if possible)* | | 12222 Merit Drive, Suite 1500, Dallas, TX 75251 | |
| *Monitor Suite (M-F 8a-5p)* | | 12222 Merit Drive, Suite 1500, Dallas, TX 75251 | |
| *Long term storage* | *Iron Mountain* | 4117 Pinnacle Point, Dallas, TX 75211 | |
| *Mary Crowley Medical Research Center IRB* | | 12222 Merit Drive, Suite 1500A, Dallas, TX 75251 | |

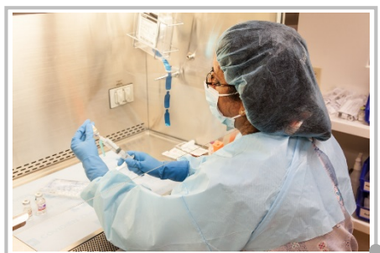
| ClinicalTrials.gov | | | |
|---|---|---|---|
| Contact: | Minal Barve, MD | P:(972) 566-3000 | Referral@MaryCrowley.Org |

# CLINIC FLOORPLAN











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# Mary Crowley Cancer Research Site at Medical City Dallas Hospital

| Summary of Site | |
|---|---|
| Experience | Dedicated, tertiary early phase, oncology research center, in operation since 1992. Outpatient and inpatient hospital support, and a dedicated referral and consult team. MCCR has completed phase I and phase II, industry funded studies including first-in-human, drug-drug interaction and intensive EKG monitoring studies. This site has experience using gene therapies, cytokines, cytotoxic agents, cellular therapies, small molecules, viral therapies, monoclonal antibodies, antibody drug conjugates, immune therapy, and vaccines. |
| Relationship with TOPA (Texas Oncology Physician Associates) | MCCR is an independent research facility, and TOPA has no jurisdiction over the trials performed at this site. TOPA also performs research in the North Texas area, but they typically perform later phase research, where MCCR specializes in early phase I and II. MCCR tries not to perform the same studies that another TOPA site in North Texas is performing. MCCR is a 100% referral based center that receives patients from other practices in the North Texas area, so any other sites in North Texas could affect MCCR's ability to enroll/ participate on the trial. Please inform MCCR of other sites in the North Texas area. |
| Clinic Hours | Typical hours are from 7am to 5pm. Extended hours (PKs will be completed in clinic up to 12 hours post dose) and weekend hours (for PKs, vital signs, and ECGs) can be accommodated. Meetings occur weekly to ensure adequate staff coverage for the coming week. |

| Staff/ Training | |
|---|---|
| Physicians/ Mid-levels | In addition to the lead PI, sub-investigators are listed on the 1572 (see Contact Sheet). |
| Pharmacists | (3) dedicated research pharmacists available to provide coverage—2 full-time pharmacists and 1 part time pharmacist<br>(2) Pharmacy techs are also available full-time. |
| Clinical Research Nurse | (1) Full time Clinical Research Nurse is assigned to each study. Managers and/or other staff in position provide backup coverage. |
| Clinical Research Coordinator | (1) Full time Clinical Research Coordinator is assigned to each study. Managers and/or other staff in position provide backup coverage. |
| Data Coordinator | (1) Full time Data Coordinator is assigned to each study. Managers and/or other staff in position provide backup coverage. |
| Treatment Nurses | All Treatment nurses are trained to every study and will perform their duties for all studies. Managers and/or other staff in position provide backup coverage. |
| Laboratory Technician | All lab technicians are trained to every study and perform their duties for all studies. Managers and/or other staff in position provide backup coverage. |
| Referral and Consult Team | A dedicated referral and consult team reviews the patients' medical record and pre-screens for clinical trial options with the consulting investigator. The Trial Enrollment Specialists will facilitate screening of subjects for trials. |

| Subject Participation | |
|---|---|
| Overview of Patient Population | This site is strictly a referral-based center and no standard of care treatments are provided unless a protocol requires it or it is palliative care while a subject is on a clinical trial. MCCR sees patients (ages 13+) after they have exhausted SOC options with their primary oncologist |
| Recruitment | MCCR has connections with over 300 physicians in the North Texas region that will refer to this site. The referring physicians provide SOC and will refer their patients after SOC options are completed. This site stays in communication with the primary care provider and will send patients back to their provider if no available studies are open. Subjects will start to be identified within 2 weeks prior to estimate of open to enrollment. |
| Patient Location | Most of the patients are located within the DFW area. Travel and lodging assistance for those that have extensive visits and/or are further away may be requested. |

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| Subject Participation | |
|---|---|
| Advertising | The Outreach Team connects with the referring physicians to provide information regarding open trials. Please supply abstracts or presentations that have reported early findings related to the IP and the efficacy of the IP to provide to the referring physicians. Patient advertising material is not requested. Referring physicians are provided with the Mary Crowley iPhone app/website to easily see the trials available. The app is searchable by mutation/biomarker, indication, drug type, and phase, and will provide the MOA, key I/E criteria, objective, and referral contact information. |
| Diversity | Strategic outreach to local community organizations that target minority and underserved populations raise awareness of this site and the studies. The multilingual staff provide a welcoming atmosphere for all patients. Additionally, the MCCR benevolence fund (provided by philanthropic donations) allows low-income patients to apply for financial assistance to cover patient costs not covered by the clinical trial budget. |
| Subject Retention | The patient has access to a social worker who uses multidisciplinary approach to evaluate and offer patients, their family and/or caregivers assistance with anything ranging from psychosocial support, financial, insurance, social security or anything outside the scope of medicine. Providing these services help to ease the burden to facilitate adherence to the clinical trial. The social worker will also coordinate application for the benevolence fund. |
| Consent Contents | This site uses the Mary Crowley Medical Research Center IRB approved template. This template meets all the FDA (CRF Title 21 Part 50) and GCP, required and optional, regulations. There is specific risk and procedure language attached to the end of the template. The IRB has agreed upon this specific language to use across all studies.<br>All consents have a "Process Page" that documents date, time, version, type of consent (initial, re-consent, phone consent); any SOC procedures performed prior to consent that will be used for the study, and any other notes applicable.<br>The last page of the consent is the HIPAA agreement. |
| PI Treatment Oversight | Physicians (see contact sheet) rotate clinic days throughout the week ensuring 1-2 physicians in clinic each day while Mid-Levels (see contact sheet) are available every day. A meeting occurs daily to review subjects scheduled that day and subjects scheduled the next day. Additionally, all active subjects are reviewed weekly by investigators, clinic staff, and study team to communicate subject status (AEs, treatments scheduled, disease status, etc.). |

| On- Site Facilities/ Capabilities | |
|---|---|
| Exam Rooms | (4) Private rooms used for physical exams, consultations, screening, and scan review visits and are approved for IBC treatments.<br>(2) Additional rooms are approved for IBC treatments. The isolation room has a personal bathroom, while the procedure room has the anti-room. Each exam room is labeled with a list of IP that should be given in these rooms. Rooms are equipped with additional supplies (booties, gowns, sharps container, etc.). |
| Intake Procedures | Vital signs and pre-treatment blood draws will be completed in the intake room. Equipment includes:<br>• Oral Thermometer<br>• Automatic Blood Pressure and pulse machine<br>• Adult Blood Pressure Cuff and Calibrated Manometer<br>• Pulse Oximeter<br>• Weight Measurement Device (Scale)<br>• Height Measurement Device (Stadiometer) —No shoes: Height and weight taken by MCCR is used to calculate BMI or kg to eliminate any doctor-to-doctor discrepancies. |
| Treatment Area | • (13) comfortable infusion chairs<br>• (15) B-Braun Infusomat® pumps<br>• (1) Ultrasound machine<br>The treatment area is located next to the pharmacy for easy access. Patients are provided with puzzles, TV, literature, blankets and snacks for comfort. |

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| On- Site Facilities/ Capabilities | |
|---|---|
| Biosafety Level 2 | Staff are OSHA/BBP/Safety trained. A copy of the NIH Guidelines for Research Involving Recombinant DNA Molecules as well as the biohazard/biologic waste policy is available. All clinic areas, including the laboratory and pharmacy, are equipped to handle biologics. Additional equipment—safety needles (reusable sharps are not used), (4) eyewash stations, fully closeable doors, one piece (seamless) flooring, spill kits including decontamination chemicals (surfaces decontaminated daily), personal protective equipment, biological safety cabinets, and biohazard warning labels. |
| ECG monitoring | (2) Site 12 Lead Electrocardiogram (EKG/ECG) machines calculate Frederica and Bazett. If the ECG is study-specific and provided by the sponsor, a rolling cart is also requested for ease of mobility. Holter monitoring can be performed if the sponsor provides equipment. |
| Kit Storage | A large kit storage room is located on site. Clinical Research Coordinators are responsible for routinely checking for expired kits. |

| Mary Crowley Cancer Research Laboratory | |
|---|---|
| Equipment | Blood processing equipment includes:<br>• (1) microscope for counting PBMCs<br>• (2) refrigerated swing bucket centrifuges with movable cylinders (up to 3000 RPMs)<br>• (2) ambient swing bucket centrifuges (up to 15000 RPMs: micro, 5000 RPMs: regular)<br>• (1) vortex mixer<br>• (1) laminar flow hood<br>• (2) -80°C Freezers (alarm sounds at <58° to >86° Celsius)<br>• (1) -20°C Freezer (alarm sounds at <28° to >12° Celsius)<br>• (2) 2-8°C Refrigerator (alarm sounds at <2° to >8° Celsius)<br>• (1) small -80°C chest with dry ice (ordered every 2 weeks or as needed)<br>Additionally, liquid nitrogen can be accommodated but the sponsor would need to provide all equipment, including the tank, refills and Dewar's. |
| Central Lab Processing Areas | Two (2) self-contained lab areas are located inside the clinic to decrease time between blood draws/urine collection and processing. The labs are equipped to prepare the samples for shipping. Samples can be stored but it is preferred to batch ship at least once per month. Backup samples are stored separately from primary samples. Same day processing and shipping is possible. |
| Archival Tissue/ Tissue Procurement | Archival tissue can be provided via slides (preferred no blocks). On average, obtaining tissue from a pathology lab takes 21 days. Most patients have archival tissue.<br>Mary Crowley IATA trained clinic staff will go to IR to collect the tissue from the interventional radiologists. |

| Mary Crowley Cancer Research Investigational Drug Repository | |
|---|---|
| Experience | The MCCR IDR has experience with gene therapies, cytokines, cytotoxic agents, cellular therapies, small molecules, viral therapies, monoclonal antibodies, antibody drug conjugates, immune therapy, and vaccines. The staff at MCCR IDR also have experience with many EDCs and IXRS systems. |
| Security | This is a dedicated research pharmacy. |
| Blinded Studies | This site has experience with blinded studies. The Pharmacy can be blinded or unblinded, and will ensure that the appropriate drug is provided according to sponsor blinding instructions. |
| Closed System Transfer Devices | CTSDs are only required at this site for standard of care chemotherapies. The brand used is by OnGuard (e.g. Tevadator). CSTDs are not used on IP unless requested by sponsor. |

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| On- Site Facilities/ Capabilities | | |
|---|---|---|
| | Equipment | The pharmacy equipment includes:<br>• (3) Class II, Type A2 laminar flow hoods. One is used for biologics, one for non-genetically modified drugs, and the last one for any non-chemotherapeutic such as pre-medications or palliative care medications.<br>• (2) -80°C freezers with dry ice<br>• (1) -20°C freezer<br>• (2) 2-8°C refrigerators<br>• (1) hot water/ice bath processing<br>Additionally, liquid nitrogen can be accommodated but the sponsor would need to provide all equipment, including the tank, refills, and Dewar's. |

| Facility Specific Procedures | |
|---|---|
| Temperature Monitoring | All temperature-monitored equipment have emergency backup power via generators. The pharmacy, laboratory, kit storage areas, refrigerators, and freezers are monitored via 2 probes linked to two different continuous monitoring systems. Continuous monitoring reports will only be provided in the event of an excursion |
| Patient Emergency | A cart with an AED and portable oxygen is located in the treatment area. The emergency medications are kept under lock and key. In addition, there is walled oxygen in the treatment area and IV medications available at the pharmacy.<br>Staff has experience in handling cytokine release syndrome and other infusion reactions. |
| Protection | Medical charts are electronically stored and backed up to multiple servers. The building is protected by sprinkler and extinguishing systems. All temperature-monitored equipment has emergency backup power via generators. |
| Recovery | If any paper documents are devastated, MCCR 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. |

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

| FDA Audits | |
|---|---|
| MCCR FDA audits | The regulatory authorities have audited MCCR 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. Additionally, you will see that the site is listed as Texas Oncology PA, which Mary Crowley used to complete research under. |

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# Off Site Facilities/Vendors

| Facilities Used for Special Procedures<br>*Please note that this list is not comprehensive. It includes commonly requested vendors. Please check with the Study Development Manager for other vendors affiliated with Mary Crowley. | | |
|---|---|---|
| Laboratory | Procedures | Processing blood, urine, stool etc. samples. |
| | Distance | Located within MCD Hospital (walking distance) |
| Radiologist (Tumor Measurements) | Procedures | X-ray, FDG-PET, FDG-PET/CT PET Scan, Fluoroscopy, CT scan (Spiral and Helicoidal), EKG, ECHO, MUGA, Bone Scan, Dual- Energy X-ray Absorptiometry (DEXA) or Bone Densitometry, Mammography, MRI, MRA, MRS, DCE-MRI, and DCE-Ultra can be taken. Two radiologists review all site's scans and measurement of lesions for tumor assessment. Both radiologists work closely to eliminate doctor-to-doctor discrepancies. Site has experience with RECIST, mRECIST, irRECIST, PCWG, and RANO. |
| | Distance | Located within MCD Hospital (walking distance). Other facilities may be used if patient's insurance dictates so. |
| Nuclear Medicine | Procedures | Infusion and scanning of investigational products requiring a licensed radio-nuclear pharmacist. |
| | Distance | This facility is located about 15 minutes from MCCR clinic, but site staff can be sent to this facility if necessary to complete study related procedures. |
| | Scheduling | Radiologists can review scans and provide a report within 24-48 hours |
| Leukapheresis | Procedures | Leukapheresis of patients' blood and shipment to sponsor for further processing |
| | Distance | Located about 5-10 minutes distance. |
| | Scheduling | Site receives reports or notes within 24-48 hours |
| Interventional Radiology | Procedures | Injection of IP by radiologist(s) trained to the specific study for deep lesions requiring ultrasound or CT/MRI guidance. (Easily accessible lesions can be performed in clinic—i.e. cutaneous lesions) |
| | Distance | Located within MCD Hospital (walking distance) |
| Overnight Stays / Oncology Ward | Procedures | Used for any overnight, inpatient observation. PKs will be completed in MCCR clinic up to 12 hours post dose, and MCCR staff will collect any subsequent central labs on the oncology ward. PI or designee will provide training/instruction to hospital staff prior to transferring patient. If overnight hospitalization is required, the study will also require review by the hospital IRB (Medical City Dallas Hospital) |
| | Distance | Located within MCD Hospital (walking distance) |
| Next Generation Sequencing | Procedures | Next Generation Sequencing is offered to every appropriate patient if they haven't already received it. Site typically uses Tempus, Foundation Medicine, Guardant, or Caris. Tumor Tissue from a recent biopsy will be requested and sent in for testing. A blood sample can also be taken to receive basic genetic results. |
| Bone Marrow Biopsies | Procedures | Bone marrow biopsies can be accommodated, if necessary. Samples can be evaluated for the following: cytogenetics, IHC staining, FISH (for ALL, AML, and MDS probes), SISH (for kappa, lambda, and EBV), and Flow cytometry. |
| | Distance | Located within MCD Hospital (walking distance) |
| Tumor Biopsies | Procedures | Surgeons and/or Interventional Radiologists will perform tissue procurement and any ultrasound or CT guided biopsy. (Easily accessible lesions can be performed in clinic—i.e. punch biopsies) |
| | Distance | Located within MCD Hospital (walking distance) |
| Cardiologist | Procedures | Echocardiograms/ MUGA |
| | Distance | Located within MCD Hospital (walking distance) |
| Ophthalmologist | Procedures | Eye exams that cannot be done by a physician |
| | Distance | Located within MCD Hospital (walking distance) |
| Dermatologist | Procedures | Skin exams that cannot be done by a physician |
| | Distance | Located within MCD Hospital (walking distance) |

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# Administrative Processes

| Staff/ Communication of Trial Information to Sites | |
|---|---|
| Clinical Trial Manager / Lead | (1) Full time Clinical Trial Manager (CTM) or Clinical Trial Lead (CTL) 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 CTM/CTL 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 Regulatory Affairs Manager, CTM, or CTL 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 subjects 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. Before access is given to patient rosters in the EMR and yearly thereafter, Texas Oncology requires completion of Compliance Training. MCCR specific training is not required, but MCCR staff can provide a verbal training if assistance is necessary. Redacted source may be sent on a limited basis for SDV requirements to be met for Data Cuts. Prior approval and additional compensation for out of scope work required. |
| 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 and additional compensation for out of scope work. 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 regulatory authorities have audited MCCR 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 regulatory authorities audited the Mary Crowley Medical Research Center IRB 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. |

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| 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 |
| 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 obtaining activation. This provides a goal date for all teams involved to ensure activation occurs 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 the sponsor requests wet ink signatures, 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<br>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).<br>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.) |

| Medical City Plano IRB | |
|---|---|
| Necessity | Not required for all studies. |
| Full Name & Address | Medical City Plano Institutional Review Board<br>3901 W. 15th St, Plano, Texas 75075 |
| Qualifications | This is a local IRB and meets all FDA and OHRP requirements. Federal Wide Assurance #:FWA00014788. FDA registration number: IRB00007165 |
| 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. |