

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 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)	We are an independent research facility, and TOPA has no jurisdiction over the trials that we perform. 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. We are a 100% referral based center that receives patients from other practices in the North Texas area, so any other sites in North Texas could impact our ability to enroll/ participate on the trial. Please keep us informed of any other sites in the North Texas area, so that we can evaluate any competition.

Staff/ Communication of Patient Safety

Physicians/ Mid-levels	In addition to the lead PI, we have several sub-investigators listed on the 1572 (see Contact Sheet).
Pharmacists	<ul style="list-style-type: none"> • (2) dedicated research pharmacists available to provide coverage—1 full-time pharmacist and 1 part time pharmacist • (2) pharmacy techs are also available full-time.
Study Staff	<p>Each study is assigned a dedicated clinical research team which includes the following:</p> <ul style="list-style-type: none"> • (1) Clinical Research Nurse - full time (Manager or another CRN trained to the study provides back up coverage) • (1) Clinical Research Coordinator/Assistant responsible for clinical performance of the study - full time (Manager or another CRC trained to the study provides back up coverage) • (1) primary Data Coordinator and then all other Data Team members, including the Data Managers are backup <p>All other positions (treatment nurses, pharmacy staff, lab technicians, patient coordinators) are trained to every study and will perform their duties for all studies we conduct. Back up coverage is provided if necessary by managers and/or other staff in position. There is a dedicated referral and consult team that reviews the patients' medical record and pre-screens for clinical trial options with the consulting investigator. The Patient Coordinator team will facilitate screening of patients for trials. In addition to clinic staff, the central location will also have research staff.</p>
Clinic Hours	Meetings occur weekly to ensure adequate staff coverage for the coming week. Typical hours are from 7am to 5pm. Extended hours and weekend hours for PKs, vital signs, and ECGs can be accommodated.
Patient Treatment Oversight	Five Physicians rotate clinic days throughout the week ensuring 1-2 physicians in clinic each day while 2 Mid-Levels are here every day. A meeting occurs daily to review patients scheduled that day and patients scheduled the next day. Additionally, all active patients are reviewed weekly by investigators, clinic staff, and project managers to communicate patient status (AEs, treatments scheduled, disease status, etc.).

Patient Recruitment

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 patient is on a clinical trial. We see patients (ages 13+) after they have exhausted SOC options with their primary oncologist.
Recruitment	We have 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. We stay in communication with the primary care provider and will send patients back to their provider if we have no available studies. Our site will start looking for patients internally within 2 weeks prior to estimate of open to enrollment.

Patient Recruitment	
Advertising	We have an outreach team that connects with our referring physicians to provide information regarding trials open at our site. Please provide any abstracts or presentations that may explain the efficacy of the IP. We will provide this to the referring physicians. Patient advertising material is not requested. Referring physicians are provided with the Mary Crowley iPhone app/website so they can easily see the trials we have available. They can search by mutation/biomarker, indication, drug type, and phase, and they will be provided with the MOA, key I/E criteria, objective, and referral contact information.
Patient Location	Most of our patients are located within the DFW area. We may request travel and lodging assistance for those that have extensive visits and/or are further away.
Patient Retention	During the consult, screening and on study visits, the patient has access to a social worker that will assist the patient with any travel, housing or support services the patient may need. We also have a benevolence fund (provided by philanthropic donations) to assist patients with covering these costs.

Consenting/Screening Process	
Consent Contents	We use a 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 we conduct at our site. All of our 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. The last page of the consent is the HIPAA agreement.

On- Site Facilities/ Capabilities	
Exam Rooms	We have 4 exam rooms used for consult, screening, and scan review visits and are approved for IBC treatments.
Intake Procedures	Vital signs and pre-treatment blood draws will be completed in the intake room. Equipment includes: <ul style="list-style-type: none"> • Automatic Blood Pressure and pulse machine • Adult Blood Pressure Cuff and Calibrated Manometer • Pulse Oximeter • Weight Measurement Device (Scale) • Height Measurement Device (Stadiometer) –No shoes: We use the height and weight taken by Mary Crowley staff to calculate BMI or KG to eliminate any doctor-to-doctor discrepancies.
Treatment Area	<ul style="list-style-type: none"> • (13) comfortable infusion chairs • (15) B-Braun Infusomat® pumps. The treatment area is located next to the pharmacy for easy access. Patients who are required to stay for long days are provided with puzzles, TV, literature, blankets and snacks for comfort.
Additional Treatment Rooms	There are two (2) additional rooms approved for IBC treatments. The isolation room has a personal bathroom, while the procedure room has the anti-room. Each exam room is labeled and has a list of IP that should be given in these rooms. Rooms are equipped with additional supplies (booties, gowns, sharps container, etc.).
Biosafety Level 2	Staff are BSL-2 trained. All clinic areas, including the laboratory and pharmacy, are equipped to handle biologics. Additional equipment—including safety needles (reusable sharps are not used at Mary Crowley), 4 eyewash stations, fully closeable doors, seamless floors, decontamination chemicals, personal protective equipment, biological safety cabinets, biohazard warning labels, sealed rotor heads, and centrifuge safety cups—are located in areas where recombinant or synthetic nucleic acids are present.

On- Site Facilities/ Capabilities	
ECG monitoring	<ul style="list-style-type: none"> • (2) Site 12 Lead Electrocardiogram (EKG/ECG) machines calculate Frederica and Bazett formulas. <p>If the ECG is study-specific and provided by the sponsor, we will request a rolling cart for ease of mobility. We do not have a site holter monitor, but we can perform holter monitoring if provided.</p>
Mary Crowley Cancer Research Laboratory	
Equipment	<p>Blood processing equipment includes:</p> <ul style="list-style-type: none"> • (2) refrigerated centrifuges (up to 3000 RPMs) • (2) ambient centrifuges (up to 15000 RPMs for micro, 5000 RPMs for regular) • (1) hot water/ice bath processing • (1) vortex mixer • (1) laminar flow hood • (2) Dedicated, -80°C Freezers (alarm sounds at <58° - >86° Celsius) • (1) Dedicated, -20°C Freezer (alarm sounds at <28° - >12° Celsius) • (2) Dedicated, 2-8°C Refrigerator (alarm sounds at <2° - >8° Celsius) • (1) small -80°C chest with dry ice (ordered every 2 weeks or as needed) <p>Additionally, liquid nitrogen can be accommodated but the sponsor would need to provide all equipment, including the tank, refills and dewars.</p>
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. We can store samples but prefer to batch ship at least once per month. Backup samples are stored separately from primary samples.
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 of our patients (~93%) have archival tissue. For fresh tissue samples, we are equipped and trained to immediately process tissue if needed.
Mary Crowley Cancer Research Investigational Drug Repository	
Security	This is a dedicated research pharmacy.
Equipment	<p>The pharmacy equipment includes:</p> <ul style="list-style-type: none"> • (3) Class II, Type A2 laminar flow hoods to prep drugs • (2) -80°C freezers with dry ice • (1) -20°C freezer • (2) 2-8°C refrigerators <p>Additionally, liquid nitrogen can be accommodated but the sponsor would need to provide all equipment, including the tank, refills, and dewars.</p>

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 monitoring systems.
Patient Emergency	We have a cart with an AED and portable oxygen. Our emergency medications are kept under lock and key. In addition, we have walled oxygen in the treatment area and IV medications available at the pharmacy.
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, 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.

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. Additionally, you will see that the site is listed as Texas Oncology PA, which Mary Crowley used to complete research under.

Off Site Facilities/Vendors

Facilities Used for Special Procedures		
*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, PET Scan, CT scan, EKG, ECHO, MUGA, Bone Scan, and MRI can be taken. We have 2 radiologists who review our scans and measurement of lesions for tumor assessment. They both work closely to eliminate doctor-to-doctor discrepancies.
	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 our clinic, but our staff can be sent to this facility if necessary to complete study related procedures.
Leukapheresis	Procedures	Leukapheresis of patients' blood and shipment to sponsor for further processing
	Distance	Located about 5-10 minutes distance.
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 our clinic up to 12 hours post dose, and any subsequent central labs will be collected by our clinic staff 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 of 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. We typically use Tempus, Foundation Medicine, Guardant, or Caris. Tumor Tissue from their most 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.
	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
	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)