MARY CROWLEY CANCER RESEARCH
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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 impact 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/ Communication of Patient Safety	
Physicians/ Mid-levels	In addition to the lead PI, the site has several sub-investigators 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 (2) Pharmacy techs are also available full-time.
Clinical Research Nurse	(1) Full time Clinical Research Nurse is assigned to each study. Back up coverage is provided by managers and/or other staff in position.
Clinical Research Coordinator	(1) Full time Clinical Research Coordinator is assigned to each study. Back up coverage is provided by managers and/or other staff in position.
Data Coordinator	(1) Full time Data Coordinator is assigned to each study. Back up coverage is provided by managers and/or other staff in position.
Treatment Nurses	All Treatment nurses are trained to every study and will perform their duties for all studies. Back up coverage is provided by managers and/or other staff in position.
Laboratory Technician	All lab technicians are trained to every study and will perform their duties for all studies. Back up coverage is provided by managers and/or other staff in position.
Referral and Consult Team	There is a dedicated referral and consult team that reviews the subjects' 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. They see 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. The site stays in communication with the primary care provider and will send patients back to their provider if no available studies are open. The site will start looking for subjects internally 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 trials open at the site. Please supply abstracts or presentations that have reported early findings related to the IP 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	The site does strategic outreach to local community organizations that target minority and underserved populations to raise awareness of the 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.
Subject Retention	The patient has access to a social worker (SW) 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. By providing these type of services we help to ensure trial participation and compliance. The SW 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. 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. 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 Project Managers to communicate patient 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. (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: • 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 MCCR to calculate BMI or kg to eliminate any doctor-to-doctor discrepancies.
Treatment Area	• (13) comfortable infusion chairs • (15) B-Braun Infusomat® pumps • (1) Ultrasound machine 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, 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.
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: • (1) microscope for counting PBMCs • (2) refrigerated swing bucket centrifuges with movable cylinders (up to 3000 RPMs) • (2) ambient swing bucket centrifuges (up to 15000 RPMs: micro, 5000 RPMs: regular) • (1) vortex mixer • (1) laminar flow hood • (2) -80°C Freezers (alarm sounds at <58° to >86° Celsius) • (1) -20°C Freezer (alarm sounds at <28° to >12° Celsius) • (2) 2-8°C Refrigerator (alarm sounds at <2° to >8° Celsius) • (1) small -80°C chest with dry ice (ordered every 2 weeks or as needed) 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 site prefers 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 (~93%) have archival tissue. For fresh tissue samples, the site is equipped and trained to immediately process tissue if needed.
Mary Crowley Cancer Research Investigational Drug Repository	
Experience	This pharmacy has experience with gene therapies, cytokines, cytotoxic agents, cellular therapies, small molecules, viral therapies, monoclonal antibodies, antibody drug conjugates, immune therapy, and vaccines. They 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 the site for standard of care chemotherapies. The brand used is by OnGuard (e.g. Tevadator). We won't use CSTD on IP unless requested by sponsor.

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On- Site Facilities/ Capabilities		
	Equipment	The pharmacy equipment includes: • (3) Class II, Type A2 laminar flow hoods. One is used for biologics, one for non-genetically modified drugs, and the last one for premedications. • (2) -80°C freezers with dry ice • (1) -20°C freezer • (2) 2-8°C refrigerators • (1) hot water/ice bath processing 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. Our site 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 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.

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Off Site Facilities/Vendors

Facilities Used for Special Procedures *Please note that this list is not comprehensive. It includes commonly requested vendors.		
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 any subsequent central labs will be collected by MCCR 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. 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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