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)					
	Contact information for PI:	P:(972) 566-3000	F: (972) 566-3099		
1	Minal Barve, MD	Oncology/ Hematology		ML#K9724	NPI: 1245277698
2	Douglas Orr, MD	Oncology/ Hematology		ML#H7202	NPI: 1194767061
3	Reva Schneider, MD	Oncology		ML#N3295	NPI: 1487864864
4	Gilberto Jimenez-Justiniano, MD F.A.C.P	Oncology/ Hematology		ML#N0866	NPI: 1619933504
5	Jairo Olivares, MD	Oncology/ Hematology		ML#J9250	NPI: 1770520165
6	Leah Plato PA-C, MPH, CCRP	Physician Assistant		ML#PA05945	NPI: 1013161652
7	Ntombizodwa Sayi MSN, RN, AGPCNP-BC	Nurse Practitioner		ML#AP136246	NPI: 1134621683
8	Jenifer Mallow, NP	Nurse Practitioner		ML#AP133892	NPI: 1538689336

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:	Comerica Bank	NorthPark Office, Branch 783, 8850 Boedeker Street, Dallas, TX 75225		
	Account Number:	1881182214	*ABA Number:*	111000753 (SWIFT)

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

LAB KITS STORAGE

C-717

C-707

PATIENT WAITING AREA

EXAM RM 2

EXAM RM 3

EXAM RM 4

EXAM RM 1

INTAKE RM

WT/ HT STATION

REFRESHMENTS

LAB

LAMINAR FLOW HOODS

ANTE RM

LAMINAR FLOW HOOD

INVESTIGATIONAL DRUG REPOSITORY

TREATMENT AREA

ANTE RM

PROCEDURE RM

ISOLATION RM

PERSONAL BATHRM

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MARY CROWLEY CANCER RESEARCH: MEDICAL CITY DALLAS (MCD) SITE

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 authority 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.

MCD 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

Dedicated Research Staff for All Trials

Physicians/Advanced Practice Providers

In addition to the lead PI, all other investigators are listed on the 1572 as sub-investigators. See the Contact Sheet for a list of all that will be included.

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.

Treatment Nurses

All treatment nurses are trained to every study and will perform their duties for all studies. Managers and/or other staff in this 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 this position provide backup coverage.

Consult Coordinator

One (1) full time Consult Coordinator reviews the patients' medical record and pre-screens for clinical trial options with the consulting investigator. The Clinical Research Nurse will facilitate screening of subjects for trials.

Dedicated Research Staff for Individual Trials

Clinical Trial Manager/Lead

One (1) full time Clinical Trial Manager or Clinical Trial Lead is assigned to each study. They are the main point of contact and handle all study-related issues, clinical and administrative. Managers and/or other staff in this position provide backup coverage.

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Clinical Research Nurse
One (1) full time Clinical Research Nurse is assigned to each study. Managers and/or other staff in this position provide backup coverage.

Clinical Research Coordinator
One (1) full time Clinical Research Coordinator is assigned to each study. Managers and/or other staff in this position provide backup coverage.

Regulatory Specialist
One (1) full time Regulatory Specialist is assigned to each study and handle the regulatory binder, ICF creation/ maintenance, and submissions. Managers and/or other staff in this position provide backup coverage.

Data Coordinator
One (1) full time Data Coordinator is assigned to each study. Managers and/or other staff in this position provide backup coverage.

Subject Participation

Overview of Patient Population
This site is strictly a referral-supported clinic, and no standard of care treatments are given 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.

Patient Location
Most of the patients live within the DFW area. Travel and lodging aid for those that have extensive visits and/or are further away may be requested. Travel vendors provided by the sponsor can be accommodated.

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. Staff at MCCR stay in communication with the primary care provider and will send patients back to the referring physician if no available studies are open. Subjects will start to be identified within 2 weeks prior to estimate of open to enrollment.

Advertising
MCCR team members connect with the referring physicians to communicate information about 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.

Diversity
Metrics on the patient enrollment diversity can be provided upon request. A team at MCCR coordinate strategic outreach to local community organizations that target minority and underserved populations to raise awareness of this site and the studies. The multilingual staff provide a welcoming atmosphere for all patients.

Decentralized Clinical Trials
Patients can use telemedicine visits instead of coming to the clinic for consulting and unscheduled visits. This helps to ease the burden of clinical trials on patients. Local laboratories near their home can also be used for specific labs, as necessary. Additionally, this site has worked with several sponsor-provided electronic questionnaires and diaries, which can facilitate compliance and real-time monitoring of data.

ICF Language Translation
. Akorbi, the site's contracted translation service, is preferred to ensure that the ICF is translated promptly (~2 weeks). Translation certificates are provided by the translation service.

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Medical Records
An electronic medical record for patients' health records, called iKnowMed (iKM), is used. This system is Part 11 compliant (documentation can be provided). Most of the referring oncologists use this EMR, which allows staff to immediately review the patients' chart. Other records can be requested and uploaded to the EMR after enrollment.

Source Documentation
All data is directly entered into the EMR. Certain worksheets (RECIST worksheet, questionnaires, etc.) will be uploaded.

Adverse Event Capturing
Adverse Events are captured directly in the EMR. An on-call investigator is available for any AEs that a subject has after hours (phone number provided to all subjects in patient-facing materials.).

Principal Investigator Oversight
Physicians (see Contact Sheet) rotate clinic days throughout the week ensuring 1-2 physicians in clinic each day while Advanced Practice Providers (see Contact Sheet) are available every day. A meeting occurs daily to review subjects scheduled that day and subjects scheduled the next day.

Site/Sponsor calls
Regular study specific calls can be accommodated when subjects are actively on study. It is preferred that these occur in the afternoons to avoid busy clinic mornings. In the event the PI cannot join the call, an Investigator, Clinical Research Nurse, Clinical Research Coordinator, or Clinical Trial Manager will join. If none is available, an email will be sent prior to the call with subject updates or responses to review of cohort data.

On-Site Capabilities: Medical City Dallas Site

Exam Rooms
Four (4) private rooms used for physical exams, consultations, screening, and scan review visits and are approved for IBC treatments. Two (2) additional rooms are approved for IBC treatments. The isolation room has a personal bathroom, while the procedure room has an ante-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.).

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 Investigational Drug Services (IDS), are equipped to handle biologics. Additional equipment includes safety needles (reusable sharps are not used), four (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.

Intake Procedures
Vital signs and pre-treatment blood draws will be completed in the intake room. Equipment includes:
- Oral Thermometer
- Automatic Blood Pressure and pulse machine
- Adult Blood Pressure Cuff and Manometer
- Pulse Oximeter
- Weight Measurement Device (Scale)
- 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
- Thirteen (13) comfortable infusion chairs
- Fifteen (15) B-Braun Infusomat Space IV pumps
- Two (2) B-Braun Perfusor Space Syringe pumps
- One (1) Ultrasound machine

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The treatment area is located next to the IDS for ease (see Floor Plan). Patients are provided TV, literature, blankets, and snacks.

ECG monitoring

Two (2) site 12 Lead Electrocardiogram (ECG) machines calculate Frederica and Bazett. If the ECG is study-specific and sponsor-issued, a rolling cart is requested for ease of mobility. Holter monitoring can be performed if the sponsor provides equipment. Central submission will be completed daily, if requested by the sponsor.

Lab Kit Storage

A large kit storage room is located on site (see Floor Plan).

Mary Crowley Cancer Research Laboratory

Equipment

Blood processing equipment includes:

- Two (2) refrigerated swing bucket centrifuges (up to 5000 RPMs (4000xg): tubes up to 10mL tubes)
- Two (2) ambient swing bucket centrifuges (up to 5000 RPMs (4000xg): regular tubes up to 50mL)
- One (1) microscope
- One (1) vortex mixer
- One (1) laminar flow hood
- Two (2) -80°C Freezers (alarm sounds at <58° to >86° Celsius)
- One (1) -20°C Freezer (alarm sounds at <28° to >12° Celsius)
- Two (2) 2-8°C Refrigerator (alarm sounds at <2° to >8° Celsius)
- One (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 supply 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.

Mary Crowley Cancer Research Investigational Drug Services

Equipment

The IDS equipment includes:

- Three (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.
- Two (2) -80°C freezers with dry ice
- One (1) -20°C freezer
- Two (2) 2-8°C refrigerators
- One (1) hot water/ice bath processing

Liquid nitrogen can be accommodated but the sponsor would need to supply all equipment (e.g., tank, refills, Dewar's).

Experience

The MCCR IDS 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 IDS also have experience with many EDCs and IRT systems.

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Security
This is a dedicated research pharmacy.

Drug Accountability
Vestigo (IDS software) captures core information seen in NCI drug accountability logs. Additional information can be collected as needed.

Blinded Studies
This site has experience with blinded studies.

Closed System Transfer Devices
CTSDs are only required at this site for standard of care chemotherapies. CSTDs are not used on IP unless requested by sponsor. The brand used is by OnGuard (i.e., Tevadator).

Site Specific Procedures

Temperature Monitoring
All temperature-monitored equipment has emergency backup power via generators. The IDS, laboratory, kit storage areas, refrigerators, and freezers are monitored via 2 probes linked to two different continuous monitoring systems. The primary monitoring system is Rees Scientific, and the backup monitoring system is Temp@lert. Staff also complete manual spot checks, which are saved historically for review by CRA/monitors. Continuous monitoring reports will only be provided in the event of an excursion.

Calibration
All equipment is calibrated annually in January. Records can be provided upon request.
- Electrical Calibration is performed by Cumberland.
- Aldinger performs calibration for scales, water baths, and centrifuges.
- Titan Tech inspects the laminar flow hoods.
- All other calibrations are performed internally.

The following items are exceptions:
- Laminar Flow hoods are maintained every 6 months for BSL-2 certification.
- Rees temperature monitoring is calibrated annually in July by Rees Scientific.

Data Entry

Access
At site selection, access for all Data Team members including the Data Manager is requested. This helps to ensure that there is no lag in data entry should the Primary DC have absences due to illness or vacation. The backup DC also assists with data entry when there are frequent visits/high accrual to maintain the timeliness of data entry and query resolution.

Experience
Site has experience with RAVE, Inform, Oracle, Data Labs, iMedNet, Tempo and many others, including custom EDCs.

Monitoring
General monitoring will occur at our Administrative Office's monitoring suite. However, an additional monitoring location at the clinic is available for investigational product and lab kit reconciliation. The clinic monitoring suite has a copier and four 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. Monitoring visits that require a site tour need to be scheduled prior to the visit, but a virtual tour of our clinic is available at marycrowley.org/pharma. Please see our Administrative Office's *Monitoring* section for more information on monitoring at MCCR.

Monitor's access to the EMR
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 verbal training if assistance is

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necessary. Redacted source may be sent on a limited basis for SDV requirements to be met for Data Cuts. Prior approval and compensation for this out-of-scope work is required.

Remote Monitoring

he same access that is provided on-site, can be provided via remote access. Remote monitoring may be required in certain circumstances (e.g., Pandemic) to protect patients and site staff.

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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. Please check with your MCCR contact for other vendors affiliated with Mary Crowley.

Local Laboratory

Procedures

Processing blood (CBC/hematology, CMP/chemistries), urine, stool etc. samples for safety (treatment labs). Typical labs performed are included in the Test Menu website. Additional labs outside of what is noted on this menu, may be performed. Please reach out to your MCCR contact if the lab is not listed.

Note: For processing and preparation of central labs for shipping see above section
Mary Crowley Cancer Research Laboratory

Distance

Located within MCD Hospital (walking distance)

Timelines

Labs are automatically integrated into the EMR. The treatment labs for immediate provider assessment are printed out and signed off for acknowledgement of "okay to treat," and these will be uploaded into the EMR. An investigator will review all other labs electronically.

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 are available to 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, iRECIST, PCWG, Lugano and RANO.

Distance

Located within MCD Hospital (walking distance). Other facilities may be used as patient's insurance dictates.

Timelines

Radiologist can review scans within 24-48 hours of the assessment. Investigators will then assess tumor burden given the radiologist's measurements. Worksheet will be uploaded in the EMR within 1 week of the scan. Site can send scans to central radiologist if required per protocol.

Cardiologist

Procedures

Echocardiograms/ MUGA

Distance

Located within MCD Hospital (walking distance)

Timelines

Turnaround time for report is typically 24-48 hours

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Ophthalmologist

Procedures
Eye exams that cannot be done by a physician (e.g. indirect fundoscopic exam, visual acuity, visual field exam, tonometry, slit lamp)

Distance
Located within MCD Hospital (walking distance)

Timelines
Turnaround time for the report is typically 24-48 hours

Dermatologist

Procedures
Pathological determinations or dermatology referrals per protocol

Distance
Located within MCD Hospital (walking distance)

Timelines
Turnaround time for the report is typically 24-48 hours, except pathology may take longer.

Overnight Stays / Oncology Ward

Procedures
Used for any overnight, inpatient observation. PKs are 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 patient transfer. Medical City Plano IRB is required for trials with overnight hospitalization.

Distance
Located within MCD Hospital (walking distance)

Timelines
Overnight stays will be scheduled in advance.

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.

Distance
Not applicable. Biopsies will be taken at IR, or previous archival tissue will be sent. Patient does not travel.

Timelines
Typical turnaround time is 2 weeks for blood sample and 4 weeks for tissue samples.

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— punch biopsies

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Distance
Located within MCD Hospital (walking distance)

Timelines
Biopsies are scheduled within 2 weeks. Typically, the pathology report is available within 72 hours and the block is available within 5 business days.

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)

Timelines
Turnaround time for report is typically within 72 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). IP is transferred on a rolling cart with MCCR staff present.

Timelines
Appointments are pre-scheduled after screening. MCCR staff are present for injections and collect data for EMR entry.

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 travel to this facility if necessary to complete study related procedures.

Timelines
Site receives reports or notes within 24-48 hours.

Leukapheresis

Procedures
Leukapheresis of patients' blood and shipment to sponsor for further processing.

Distance
Located about 5-10 minutes distance.

Timelines
Site receives reports or notes within 24-48 hours.

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Administrative Processes

Training
CVs, medical licenses, and other training documentation can be provided for all staff after site selection.

Study Specific Training

Monitoring

Description of Monitoring Facilities (Administrative Office at Merit Tower)
The monitoring suite has a copier and twelve 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.

Scheduling a Monitoring Visit
The MCCR SOPs require a visit every 4-6 weeks if there are active subjects. Monitoring hours are from 8am-5pm (M-F). All visits are scheduled through the Research Operations Coordinator (they will coordinate PI meeting, lab, IDS, 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.

Risk-Based Monitoring
Monitoring via risk-based monitoring strategies is encouraged. Plans for risk-based monitoring, data queries and data deadlines should be discussed with the data coordinators during initiation of the trial.

Regulatory Documentation

Electronic Investigator Site Files (eISF)
The MCCR regulatory binders are kept electronically in Florence (Part 11 compliant). Monitor/CRA visit logs will be kept for the duration of the trial, but after finishing the site's participation in the study, logs will be uploaded to the eISF binder and shredded. Signed, original consent forms are available for review at each monitoring visit.

Monitor/CRA eISF Access
At Site Initiation, Monitors/CRAs will be provided with a unique username and password sent to their email. After a brief 30 min training, monitors will have 24/7 access. The site will not provide documents via email to the CRA monitor, and instead must be collected by logging into the Florence e-Reg.

CRO Regulatory Portals
The site prefers to have a monitor/CRA upload documents into the CRO/Sponsor regulatory portal. The site can perform this task, but there will be an extra charge for these services.

Patient Safety Reporting

IND Safety Reports
To ensure timely review of IND safety reports, please send to your Regulatory Specialist and Safety@MaryCrowley.Org. Only IND Safety Reports that meet the definition of an Unanticipated Problems (UP) are required to be reported.

Protocol Deviations
Site will follow IRB specific processes for designation and reporting of protocol deviations.

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FDA Inspections

MCCR FDA Inspections
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 used to complete research under.

Quality Assurance
Additionally, an internal department will review any issues brought to their attention and review processes for potential improvement or training.

Disaster Recovery Plan

Study Startup (SSU) Timelines

Overall
The site can typically open traditional studies within 10 weeks and Just-in-Time trials within 2 weeks. SSU timelines for traditional trials may be expedited with Sponsor/CRO timeline commitments and/or master CTA / master rate cards.

Required Documents
For the site to begin startup, please provide the Protocol, IB(s), Sponsor ICF template, 1572, FDQs, Patient ID card (site template can be used if sponsor does not have one), any other patient facing documents, and date the Study May Proceed letter was received or the FDA/IRB Parallel Review LOA.

Regulatory Review
See the "Additional Review Committees" section below to determine impact on startup timelines

SIV Dates
SIV will be set about 1-2 weeks post expected last IRB approval release date (either MCMRC IRB or MCP 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 to review a study in parallel with FDA review to help expedite timelines. While FDA changes may not be required, FDA revisions may 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 site requirement to start working on this study.

Just In Time
JIT trials identify the patient for a trial prior to developing the study. This site has the capabilities to open a JIT trial. 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 FE CTA is not contingent on the IRB approval), but the goal is to have this in place by SIV. Timelines vary depending on responsiveness of the sponsor but averages 10 weeks. If utilization of a previously negotiated master contract is allowed and/or sponsor/CRO provides accelerated review and response, timelines are greatly reduced.

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Required Language

Mutual confidentiality and sponsor indemnification are the required sections, but language can be negotiated.

Insurance Coverage

Mary Crowley has general liability coverage of 1 million per occurrence and 2 million in aggregate, as negotiated in CTA. The Investigators carry professional liability coverage of 1 million per occurrence and 3 million in aggregate, as negotiated in CTA.

Number of Contracts

There is only one 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 a standard Letter of Indemnification needed if the CRO is not able to bind the sponsor to the agreement. Institution will hold all other contracts necessary for running the trial.

Signatures

There is a quick signature process, with multiple designees (CEO, PI, or others) that are 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 if a shipping label is provided. There are no other reviews that must occur between finalization and signature.

Study Start Up Fees

Study startup fees are billed upon contract execution.

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Review Committees

Mary Crowley Scientific Review Committee

Contact

Mary Crowley Cancer Research Scientific Review Committee

12222 Merit Drive, Suite 1500, Dallas, TX 75251

The sponsor cannot directly contact the SRC. All communication should be directed through the site staff.

Qualifications

The Executive Medical Director, Principal Investigator, Sub-Investigators, and key clinic staff will attend.

Impact on Startup Timelines

Approval will be released within 1-2 business days of the meeting. Meetings are held once per week (aside from holidays and Biannual Trial Portfolio Review). From submission of documents to SRC approval released, this process is expected to take 1 week. This is required prior to (aka sequential) starting any development tasks (preparing IRB submission, Budget, Contract negotiations, etc.). This can be submitted prior to site selection to ensure faster development timelines.

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Mary Crowley Medical Research Center IRB

Necessity

Site will determine if the Central IRB or this IRB must be used once all documents are provided.

Contact

Mary Crowley Medical Research Center Institutional Review Board

12222 Merit Drive, Suite 1500, Dallas, TX 75251

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.

Impact on Startup Timelines

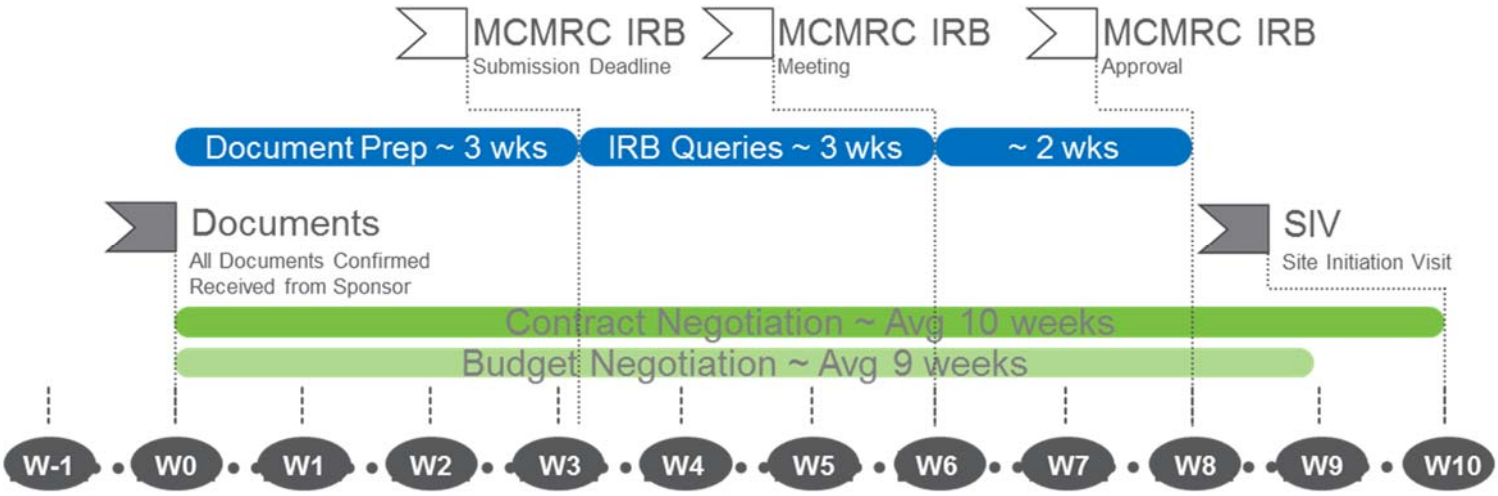
Meetings are weekly aside from holidays. One meeting per month is reserved for continuing reviews (no initial protocols reviewed). From receipt of documents/site selection to IRB approval, this process is expected to take 8 weeks (3 weeks document prep, 3 weeks for IRB Queries and 10-calendar days post IRB meeting).
This review can be done in parallel with other development tasks (Budget, Contract negotiations, etc.)

Document Prep

A Regulatory Specialist will merge the MCMRC ICF template with the sponsor ICF template and create the MaryCrowley.org website description. This typically takes 1-2 weeks depending on complexity. The Sponsor will need to review and approve the ICF and website description within a week of receipt. If more time is needed, please notify us.

IRB Queries (Pre and Post IRB Meeting)

IRB members begin pre-reviewing the submission the week of the meeting. Often, they issue queries that need to be answered prior. The Sponsor will need to have all queries answered prior to the IRB Meeting to ensure timely review. IRB board members will provide any questions that came from the meeting. Approval is not contingent on the contract being signed. Once the IRB releases approval, MCCR will forward the documents, and the reviewed documents are considered finalized. The Sponsor will need to have all queries answered within 24 hours to ensure release of the approval.



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.

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Expedited Research

Research found to involve no more than minimal risk and according to 21 CFR 56.110 can be reviewed expeditiously. Less than 1 week from submission to approval.

MCMRC IRB FDA audits

The FDA inspected 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.

Consent Contents

This IRB requires use of their specific ICF 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.

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Central IRB

Necessity

Site will determine if the Central IRB or this IRB must be used once all documents are provided.

Contact

Agreements are in place for the following IRBs:

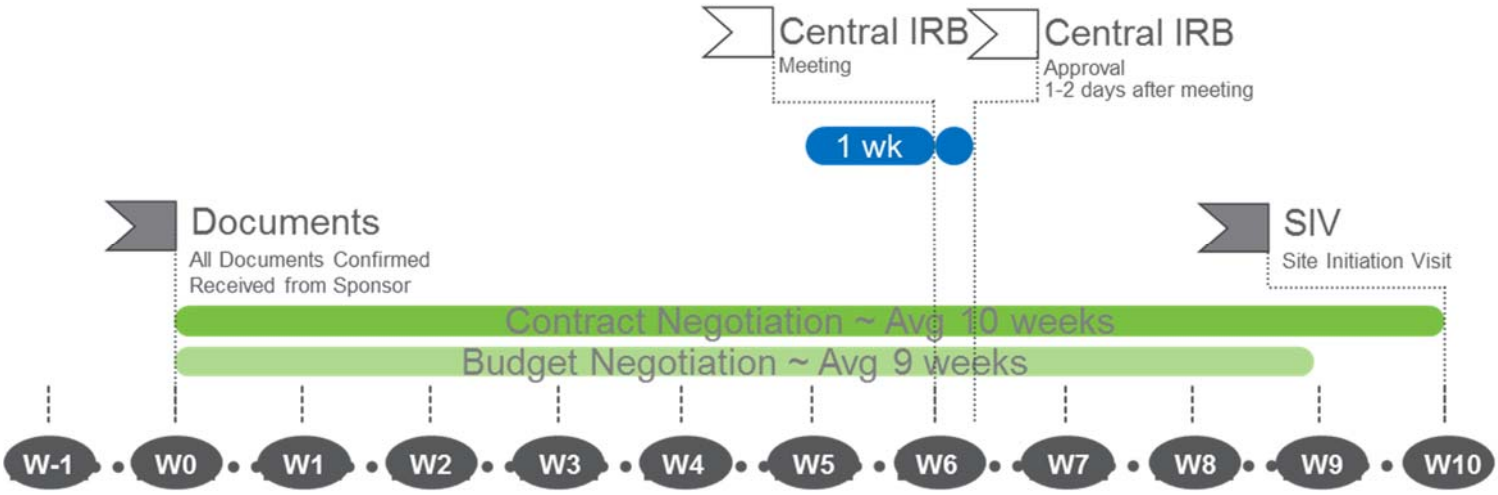
- Advarra: 6100 Merriweather Dr, Suite 600, Columbia, MD 21044
- Western Copernicus Group (WCG): 212 Carnegie Center, Suite 301, Princeton, NJ 08540, USA

Qualifications

None of the investigators are members of these IRBs.

Impact on Startup Timelines

Using a central IRB does not reduce overall startup timelines. The contract and budget negotiations will still take 10 weeks to complete. This review can be done in parallel with other development tasks (budget, contract negotiations, etc.)



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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 handles determining if IBC will need to review the trial.

Qualifications

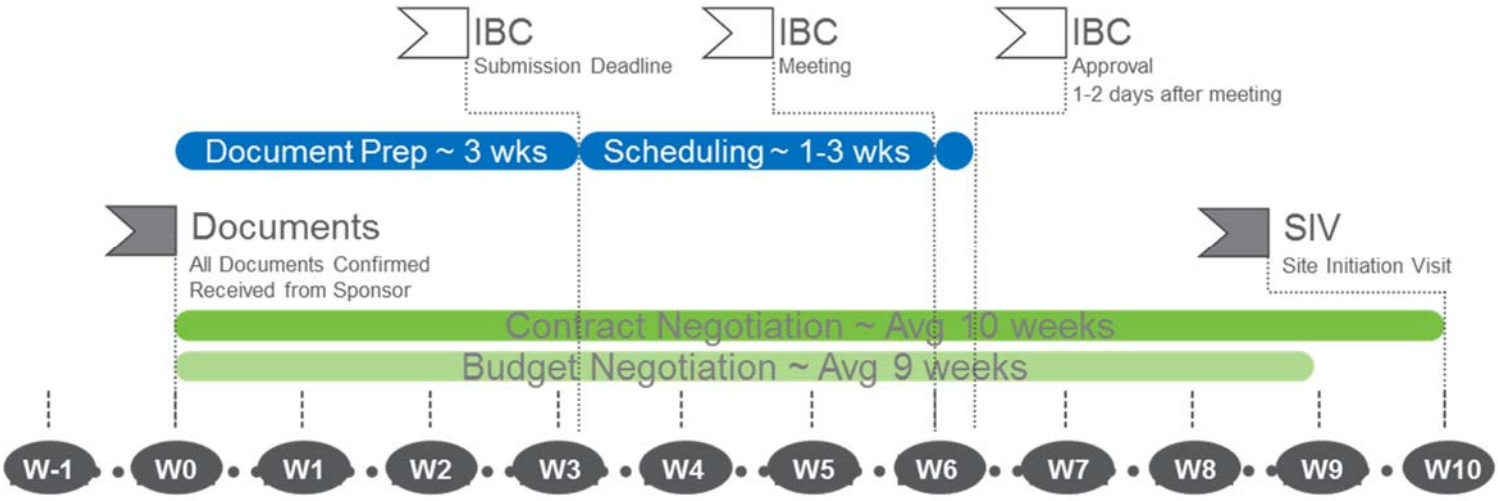
This is a central IBC and is a division of Western Copernicus Group (WCG). None of the investigators are members of this board.

Required Documents

Protocol, Investigator Brochure, Pharmacy Manual, and ICF.

Impact on Startup Timelines

Meetings are scheduled once all documents have been submitted. After the submission, approval will take about 4 weeks Meetings are scheduled on an as needed basis.
If this is required (see Necessity 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.



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Medical City Plano IRB

Necessity
Not required for all studies. The Medical City Plano IRB is only utilized for protocols, which require hospital staff to be involved in care. Overnight stays of greater than 23 hours will require review by the Medical City Plano IRB.

Contact
Medical City Plano Institutional Review Board
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. Initial preliminary review of the LOI by the Sponsor to minimize negotiation.

Impact on Startup Timelines
Meetings are held once a month. The IRB submission deadline is 2 weeks prior to the meeting. Approval is released within 24 hours. If this is required (see Necessity 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.