Thank you for your interest in opening your clinical trial at the Medical College of Wisconsin Cancer Center (MCWCC).

This document summarizes information frequently requested by study sponsors as part of routine start-up, including overviews of our internal activation process, staff, and facilities. It is our policy to provide all sponsors/CROs with this detailed information packet about our site in lieu of continually answering comparable questions on feasibility questionnaires. This saves our busy staff time and effort, and it allows us to respond to you more quickly. We are more than happy to answer study-specific questions (e.g., anticipated enrollment, competing studies) that are not covered within this document.

Adult and Pediatric Trials

We have comprehensive research programs for both adult and pediatric trials. This document focuses on information pertaining to adult cancer research. Our pediatric cancer research program is partnered with Children’s Hospital of Wisconsin and the MACC Fund Center for Cancer & Blood Disorders.

If you are interested in opening a pediatric, adolescent, or young adult trial at our site, please contact the pediatric oncology Research Manager for information regarding our pediatric staff, resources, and facilities:

Ann Bruenig (Phone: 414-955-4086; Email: abreunig@mcw.edu)

Contact Information for Adult Trials

Our Research Managers are the primary contacts for new studies. Please do not contact regulatory, budget, or contract staff until advised by the Research Manager.

<table>
<thead>
<tr>
<th>Disease Group</th>
<th>Research Manager</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I, Multi-disease</td>
<td>Katy Schroeder, RN, OCN, CCRP</td>
<td>Phone: 414.805.8843 Email: <a href="mailto:kbschroeder@mcw.edu">kbschroeder@mcw.edu</a></td>
</tr>
<tr>
<td>Bone Marrow Transplant, Cellular Therapeutics</td>
<td>Debbie Pastorek, BS, RN, CCRC</td>
<td>Phone: 414.805.6837 Email: <a href="mailto:dpastore@mcw.edu">dpastore@mcw.edu</a></td>
</tr>
<tr>
<td>Breast</td>
<td>Maria Pigsley, RN, CCRP</td>
<td>Phone: 414.805.0791 Email: <a href="mailto:mpigsley@mcw.edu">mpigsley@mcw.edu</a></td>
</tr>
<tr>
<td>Gastrointestinal, Genitourinary</td>
<td>Stacey Zindars, MS, CCRP</td>
<td>Phone: 414.805.8913 Email: <a href="mailto:szindars@mcw.edu">szindars@mcw.edu</a></td>
</tr>
<tr>
<td>Gynecology</td>
<td>Sukanya Skandarajah, BSc, CCRP</td>
<td>Phone: 414.805.5337 Email: <a href="mailto:sskandarajah@mcw.edu">sskandarajah@mcw.edu</a></td>
</tr>
<tr>
<td>Hematology</td>
<td>Paulette Jacobs, MS, CCRP</td>
<td>Phone: 414.805.4594 Email: <a href="mailto:pjacobs@mcw.edu">pjacobs@mcw.edu</a></td>
</tr>
<tr>
<td>Central Nervous System, Skin, Head/Neck, Sarcoma, Thoracic</td>
<td>May Gan, MS, MBA, PMP</td>
<td>Phone: 414.805.4380 Email: <a href="mailto:mgan@mcw.edu">mgan@mcw.edu</a></td>
</tr>
</tbody>
</table>
SITE BACKGROUND

The Medical College of Wisconsin Cancer Center (MCWCC) is a not-for-profit academic research center dedicated to reducing our patients’ cancer burden through innovative research into its causes, prevention, early detection and treatment. We are partnered with Froedtert Hospital, Children’s Hospital of Wisconsin, Clement Zablocki VA Medical Center, and the BloodCenter of Wisconsin.

Our Cancer Center is comprised of more than 250 physicians and scientists, and we are the only academic cancer center in Wisconsin’s most populous region, serving more than 2 million people. MCW has been conducting cancer clinical research for over 30 years, and we have ~145 investigator-initiated, industry- and federally-sponsored trials open to accrual at any given time. We have centralized Clinical Trials Offices with disease-specific research teams, regulatory, and administrative staff who are experienced in managing Phase I to IV studies.

Medical College of Wisconsin Cancer Center
9200 W. Wisconsin Avenue
Milwaukee, Wisconsin 53226

INVESTIGATOR SPECIALTIES and RESEARCH STAFF

Potential Investigators
Currently we have over 80 physicians on adult disease-specific research teams:

<table>
<thead>
<tr>
<th>Disease</th>
<th>Specialties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>Gynecology</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>Sarcoma</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Thoracic</td>
</tr>
<tr>
<td>Hematology</td>
<td>Skin</td>
</tr>
<tr>
<td>Central Nervous System</td>
<td>Bone Marrow Transplant</td>
</tr>
<tr>
<td></td>
<td>Cell Therapy</td>
</tr>
<tr>
<td></td>
<td>Cancer Control and Prevention</td>
</tr>
</tbody>
</table>

We have investigators representing the following modalities: hematology/oncology, radiation oncology, interventional radiology, and surgery. Additional investigator information is available upon request once an investigator has been identified (e.g., investigator’s research experience).

Study Staff
- Disease-specific research managers, research nurses, study coordinators, and research assistants- We have an average of 1-2 coordinators per disease site, each handling 5-10 actively recruiting studies, with the number varying depending on study complexity.
- Laboratory assistants who aid coordinators with processing study samples and shipping to central labs
- Dedicated education staff so that all new coordinators are trained on standard procedures. All study staff are CITI- and GCP-trained.
- Dedicated regulatory, budget, and contract specialists
- Dedicated Epic/Beacon support
- OnCore clinical trial management specialists
**TRIAL PORTFOLIO**

We have ~145 studies open to accrual at any given time (~130 interventional), encompassing all phases and sponsor types.

**PATIENT POPULATION**

**Catchment area:** MCWCC recruits participants primarily from the counties comprising Wisconsin’s eastern corridor. Most patients come from southeastern Wisconsin, but we also attract a significant number of patients from northeastern Wisconsin, particularly the Green Bay area.

**FH Population:** Over 3800 new cancer patients are seen at Froedtert every year.

<table>
<thead>
<tr>
<th>Sex ratio</th>
<th>Race/ethnicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>51.1% women</td>
<td>85.3% White, 12.6% Black, 3.1% Hispanic, 1.1% Asian</td>
</tr>
<tr>
<td>48.9% men</td>
<td>0.3% Native American</td>
</tr>
</tbody>
</table>

**Accrual:** Average of 37 interventional accruals per month, 440 per year, evenly split between liquid and solid tumor

**Recruitment:** Subjects are recruited onto trials through a variety of methods:
- Primarily through treating physicians at the Cancer Center
- Referrals from Froedtert Hospital inpatient and outpatient clinics, Froedtert Health community sites, outside physicians, Second Opinion programs
- Internal review at grand rounds, tumor boards, etc.
- Searchable website with list of actively recruiting studies: [http://www.froedtert.com/research/clinical-trials/cancer/search](http://www.froedtert.com/research/clinical-trials/cancer/search)
- Community events, cancer support groups

<table>
<thead>
<tr>
<th>Phase</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>20%</td>
</tr>
<tr>
<td>Phase II, II/III</td>
<td>38%</td>
</tr>
<tr>
<td>Phase III</td>
<td>26%</td>
</tr>
<tr>
<td>Early Phase (I, I/II)</td>
<td>20%</td>
</tr>
<tr>
<td>N/A</td>
<td>13%</td>
</tr>
<tr>
<td>Pilot</td>
<td>2%</td>
</tr>
</tbody>
</table>

Industry 38%

Cooperative Group 39%

Institutional 23%
MCWCC and Froedtert publications including print and electronic newsletters and magazines; advertisements in local media; mailings to outside physicians

Patient database, data/record mining

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**Overview of Study Start-Up Process**

- **Research Manager** receives full protocol from sponsor
- **Disease-specific Faculty Research Committee** assesses interest, feasibility
- **Scientific Review Committee** reviews for sound methodology, statistics
- **Simultaneous submission to IRB, OCRICC, etc., as well as budget and contract negotiation**
- **Once budget and contract finalized, IRB and OCRICC will approve. Then SIV and study activation.**

Our overall start-up time from receiving the full protocol to study activation is 4-6 months. In order to activate a trial at the MCWCC, the protocol must undergo reviews by disease-specific and scientific review committees, as well as the IRB. A complete and final version of the protocol is required to start the review process.

### 1. Faculty Research Committee Review

Every potential study is first reviewed by the disease-specific Faculty Research Committees (FRCs). New studies are presented at the meeting, where the patient population, competing trials, and resource availability are discussed. If a PI has not yet been identified, the committee will identify one. FRC approval is needed before moving on to the Scientific Review Committee.

**Timeline:** Each FRC meets monthly. The time to approval depends on the date of receipt of the finalized protocol in relation to the FRC cycle, but approval usually occurs within 3-4 weeks.

### 2. Scientific Review Committee

All cancer-related studies must be reviewed by the Scientific Review Committee (SRC) to ensure they are scientifically sound and feasible. This committee is composed of physicians, nurses, biostatisticians, and a pharmacist, providing a range of expertise. Studies need SRC approval in order to move on to the IRB.

For SRC review, we must have (1) the final protocol, (2) the associated Investigator Brochure(s), and (3) confirmation from sponsor that MCWCC was chosen as a participating site.

**Timeline:** The SRC meets twice per month (1st and 3rd Mondays). Protocols must be submitted at least a week in advance of the meeting. Decision letters requesting more information or revisions to the protocol usually go out to the PI within a week of the meeting. When a study is approved, an automated notification is immediately sent to the PI and Regulatory staff by our CTMS. The median time from submission to approval for external studies is 14 days.

### 3. Internal Review Board

Medical College of Wisconsin/Froedtert Hospital IRB

[http://www.mcw.edu/hrpp.htm](http://www.mcw.edu/hrpp.htm)
Pre-Submission Process
- Once a study is SRC approved, it is assigned to a Regulatory Specialist (RS) who contacts the sponsor with an approximate start time for working on the submission.
- The RS gathers required signatures on startup documents and begins drafting the submission. They will contact the sponsor with any questions.
- Once a draft submission is complete, it is reviewed by the Research Manager and any remaining questions will be sent to the sponsor.
- At that point, the RS will send the ICF to the sponsor for review and approval. If any petitions are required, the IRB typically returns its response within 2-5 days.
- Once all questions are resolved, the study can then be submitted to the IRB.

IRB Review Process
- Upon submission, an initial pre-review is performed for completeness and to determine the type of IRB review needed based on study risk. Most studies will require full committee review. Once the study team responds to any queries, a review date is set.
- Expedited IRB review is permitted for amendments meeting certain risk criteria.
- The MCW IRB does not require payment of any fees ahead of submission or prior to the release of the final approval documents; IRB fees are invoiced separately.
- IRB committee rosters: [http://www.mcw.edu/hrpp/IRBCommittees.htm](http://www.mcw.edu/hrpp/IRBCommittees.htm)

Timeline
- A draft submission is ready 4-6 weeks from the time the RS begins working on it; however, this is dependent on the responsiveness of the sponsor to questions and regulatory document needs.
- Review of the draft submission by the Research Manager takes 2-4 weeks.
- There are four IRB committees, each meet twice monthly.
- Submissions should be received by the IRB at least 2 weeks in advance of a meeting.
- Written confirmation of approval (or list of items to be amended) is provided 7-10 days after the meeting.
- It is approximately 2 months from IRB submission to approval.
- PLEASE NOTE: IRB will not grant final approval until there is a fully executed contract.

FDA Audit
The MCW IRB has been audited by the FDA. The site has not received a 483 since the formation of the CTO.

Use of CIRBs
Currently, our IRB does not permit the use of external IRBs except under specific circumstances (NCI CIRB, some phase I trials). For phase I trials, we are able to utilize an external IRB if the sponsor is using that IRB for all sites in the trial (i.e., sponsor submits documents on our behalf).

Other Regulatory Start-Up
All protocols are reviewed by Froedtert Hospital’s Office of Clinical Research and Innovative Care Compliance (OCRICC). OCRICC reviews a study’s procedures and determines whether items should be billed as standard of care or research. We also utilize vendor services for Medicare coverage analyses.

Other committees may need to review depending on the content of the protocol:
- Institutional BioSafety Committee – required if study procedures include the use of toxins, pathogens, recombinant DNA, or synthetic nucleic acids
• Radiation Safety Committee – required if study procedures include Irradiators, CT, X-Rays, DEXA scans, Fluoroscopy, and/or unsealed radioactive materials; all non-standard of care procedures also need State of Wisconsin approval
• MRI Safety Committee – required if the study procedures include any MRI scanning that is 1) not routinely performed for similar patients not enrolled in a clinical trial, 2) not performed for this study at Froedtert Hospital Radiology, or 3) not billed to the patient’s insurance as routine care cost

Timeline: Submissions to the above bodies occur prior to or simultaneous with IRB submission, so reviews occur in parallel. OCRICC will not give final approval until after IRB approval, usually within 10 days.

• All of our investigators’ CVs and medical licenses are housed centrally in our electronic files and are current (signed and dated within 2 years). We will not complete abbreviated “one-page” CVs or profiles.
• All of our investigators and research staff have completed CITI Human Subjects’ Research Training and GCP Training. Certificates are housed electronically and copies are available upon request. Our institution requires these to be current within 3 years.
• We maintain electronic and paper regulatory binders. Each study has an electronic folder stored on our secure servers. The paper binders are kept in a locked room. Paper documents are scanned and electronic copies are kept for back-up purposes.

Budgets and Contracts

Budget and contract negotiations begin upon SRC approval. We must have a copy of the full protocol beforehand. The contract, budget and IRB submission finalization can proceed in parallel; however, the contract must be fully executed before the IRB will grant final approval and issue approval letters. Budget and Contract negotiations are handled directly with Cancer Center CTO finance staff in conjunction with an institutional contracts analyst responsible for final contract negotiations and oversight. Tracked changes and rationale for edits to the Budget/CTA are required to ensure efficient negotiations.

Additionally, some services provided under our trial agreements may be conducted at our institution’s affiliate hospital, Froedtert Hospital, 9200 W. Wisconsin Avenue, Milwaukee, WI 53226. MCW and Froedtert are parties to a Research Affiliation Agreement which has been in place for 30+ years and remains current. Under this agreement, MCW is responsible for directing and controlling all research, including the training and oversight of all research activities conducted at the hospital. The integration of research amongst the two institutions is seamless, and we participate in numerous joint ventures with one another and average 300+ active studies per year which are commercially funded. With this structure in place, Froedtert Hospital will not be a party to our study agreements.

Also, our site has recently contracted several vendors for services related to clinical trial start-up and management activities, including cost/coverage analysis, budget negotiations and study calendar development. Performance of these study-related activities require the study documents (protocol, IBs, study manuals, ICF, etc.). As these activities typically commence before a study agreement is fully executed, MCW staff will work with the appropriate Sponsor representative to ensure study-specific confidentiality terms are in place between the Sponsor and MCW allowing disclosure to such a vendor, while ensuring the appropriate confidentiality terms are in place to protect Sponsors’ confidential materials. Timely cooperation with this matter will ensure no unnecessary delays occur.
The following items are required for budget development: IND number, current study protocol, investigator brochures, informed consent forms, and all applicable study manuals.

**Timeline:** The Clinical Trial Agreement (CTA), budget review, and budget negotiation can be done in parallel. On average, the CTA and budget process can take up to 4-8 weeks. The timeline is highly dependent on study complexity and protocol requirements (e.g., special labs, additional imaging), internal approvals, availability of all documents, sponsor responsiveness and receiving appropriate rationale for changes during negotiation.

**Study Activation**
- We strongly prefer to schedule Site Initiation Visits (SIVs) after we receive IRB approval.
- Every effort will be made to make the following staff available at the SIV as needed: PI, Research Manager, study coordinators, Pharmacy, Regulatory Specialist, CTO Lab assistants, Cancer Center Lab, TRU, representatives from specific specialties
- Training logs will be signed at the SIV or sent out electronically afterward.
- Delegation of Authority: The CTO employs a Master Signature Log listing all staff assigned to any protocol and their delegated tasks. A separate Protocol-Specific Delegation of Authority Log lists study staff members and any additional duties. Sponsor provided delegation logs will not be used. Copies of the master log are available to sponsors.

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**Overview of Resources and Facilities**

**INVESTIGATIONAL PHARMACY**

Froedtert Hospital's Investigational Pharmacy employs four pharmacists and three research assistants. The site is adequately staffed to perform blinded and un-blinded studies.

- Investigational drug supplies are stored in clearly labeled, designated areas, separate from standard pharmacy stock, according to conditions specified by the protocol.
- All investigational drugs are kept locked at all times and are accessible only to authorized personnel.
- Available storage: ambient, 2-8°C, -20°C, -80°C
- Daily temperature logs are maintained for drugs stored at room temperature, as well as in refrigerators and freezers. A continuous read system (Primex) triggers an alert to pharmacy staff if a refrigerator, freezer, or ambient temperature goes out of range (min/max). All refrigerators and freezers are on backup power supply; contents can be transferred to another if one goes down.
- Each study for which investigational drugs are supplied has a binder holding the latest versions of the protocol, drug shipments received and subject dosing information. Froedtert Hospital utilizes Vestigo®, a web-based software, to manage investigational drugs used in clinical trials. Vestigo® employs electronic drug accountability record forms (eDARFs), and staff will record elements required on the sponsor-provided accountability log. Records are retained for a period required by federal law or the sponsor, whichever is longer.
- Temperature probes are calibrated every 2 years, as recommended by the manufacturer, and logs are kept.
- Hours of operation: Mon-Fri 7:00am to 4:30pm (Day Hospital handles weekend/holiday dispensing)
- Copies of pharmacy SOPs are available upon request
Disposition and Destruction of Investigational Product:
All vials used for the preparation of investigational drugs will be documented as destroyed onsite on the accountability log upon usage.

Unused or expired study medications will be documented and destroyed. Used medication bottles will be documented upon return from the subject. Used containers will not be stored in the pharmacy. If the sponsor is unwilling to approve destruction of investigational drugs returned by subjects prior to monitor review, a waiver must be requested. An additional fee will be incurred for storage of subject-returned medication bottles. Pharmaceutical waste is placed in appropriate containers and processed off-site by Stericycle, Inc. Costs incurred will be charged to the study account. Complete records are maintained for all drugs returned or destroyed as a part of the perpetual inventory system.

Investigational Pharmacy shipping address:  
IDS Pharmacy, Room 3147  
Cancer Center  
Froedtert Hospital  
9200 West Wisconsin Ave.  
Milwaukee, Wisconsin 53226

CLINICAL FACILITIES

| Cancer Center Clinics | 7 disease-specific clinics located on 3 floors of the Cancer Center  
o Faith, Hope, Life, & Courage Clinics (solid tumor): 13 exam rooms, 2 consult rooms each  
o Breast Care Center: 13 exam rooms, 3 consult rooms  
o Skin Cancer Center: 4 exam rooms  
o Grace Clinic (Hem/BMT): 16 exam rooms, 3 consult rooms  
• Open Mon-Fri 8:00am to 4:30pm  
• Staffed by MDs, APPs (NP and PA), Pharmacists, Clinic RNs, Medical Assistants and Scheduling Coordinators  
• Cancer Center Laboratory  
o 14 total phlebotomy stations, staffed with 14 technicians and 2 RNs  
o Open Mon-Fri 6:20am to 4:00pm |

| Radiation Oncology | Clinic located on 3rd floor of Cancer Center  
Over 15 radiation oncologists on faculty  
MCW is a Radiation Oncology Accredited Facility through the American College of Radiology  
One of two institutions in the U.S. to install an Elekta MR-linac  
Imaging modalities include CT, PET, CT-PET, US, MRSI, and fMRI  
Radiation therapy services include the following:  
- Image-guided radiation therapy (IGRT)  
- Stereotactic body radiotherapy (SBRT)  
- Superficial X-ray therapy  
- Stereotactic radiosurgery (SRS) with Gamma Knife  
- Intensity modulated radiation therapy (IMRT)  
- Adaptive radiation therapy (ART)  
- High Dose Rate (HDR) Brachytherapy |
<table>
<thead>
<tr>
<th>Intervventional Radiology</th>
<th>Two outpatient clinics: 4th floor of the Center for Advanced Care building, 2nd floor of Cancer Center in the Courage Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>For a list of our radiation delivery, simulation, treatment planning, and motion management systems, please visit <a href="http://www.mcw.edu/Radiation-Oncology/Technology.htm">www.mcw.edu/Radiation-Oncology/Technology.htm</a></td>
</tr>
<tr>
<td>Translational Research Unit (TRU)</td>
<td>Located within the Cancer Center, the TRU is dedicated research space for more intensive procedures, complex protocols (e.g., PKs/PDs, Phase I)</td>
</tr>
<tr>
<td></td>
<td>Open Mon-Fri 7:00am to 5:00pm, with flexibility to evenings and weekends as needed</td>
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<tr>
<td></td>
<td>13 infusion bays and a sub-waiting area with room for 2 patients</td>
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<tr>
<td></td>
<td>Staffed with experienced chemotherapy infusion nurses who have received additional training in the care of patients on clinical trial</td>
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<tr>
<td></td>
<td>In unit access to a glucometer, IV pumps, EKG machine, centrifuge, -80°C freezer</td>
</tr>
<tr>
<td>Day Hospital</td>
<td>Outpatient facility located within Cancer Center for patients needing chemotherapy, blood products, or other types of infusions or advanced services which might otherwise require hospitalization.</td>
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<tr>
<td></td>
<td>Open Mon-Fri 7:00am to 7:30pm; weekends and holidays 7:00am to 4:30pm</td>
</tr>
<tr>
<td></td>
<td>41 infusion spaces, including 6 private rooms with private bathrooms, 12 private rooms with shared bathrooms, and 15 semi-private infusion bays</td>
</tr>
<tr>
<td></td>
<td>Staffed with experienced chemotherapy infusion nurses, some of whom receive additional training in the care of patients undergoing outpatient blood and marrow transplants</td>
</tr>
<tr>
<td></td>
<td>In unit access to a glucometer and IV pumps</td>
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<tr>
<td>24 Hour Clinic</td>
<td>Outpatient clinic providing urgent supportive care to oncology patients</td>
</tr>
<tr>
<td></td>
<td>Staffed by oncology nurses cross trained for both inpatient and outpatient, allows access to oncology providers (APP, MD) 24 hours a day</td>
</tr>
<tr>
<td></td>
<td>Immediately adjacent to inpatient oncology units in the Center for Advanced Care building</td>
</tr>
<tr>
<td></td>
<td>4 care spaces, access to glucometer, IV pump, EKG, etc.</td>
</tr>
<tr>
<td></td>
<td>Can be used for evening/early morning PK draws when TRU is closed</td>
</tr>
<tr>
<td>Inpatient</td>
<td>Current dedicated inpatient oncology space:</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>• BMT / Malignant Hematology Unit - 32 beds</td>
</tr>
<tr>
<td></td>
<td>• Solid Tumor / Palliative Care Unit - 30 beds</td>
</tr>
<tr>
<td>Emergency</td>
<td>We have a rapid response team for campus emergencies. We have access to Froedtert Hospital’s emergency department which is a designated Level I Trauma and Primary Stroke Center.</td>
</tr>
</tbody>
</table>

**IMAGING CAPABILITIES AT FROEDTERT**

- MCW radiologists are experienced in RECIST and other oncology interpretation criteria.
- The MCW Department of Radiology Quantitative Imaging Lab (QIL) is implementing Precision Imaging Metrics (PIM) software for tracking tumor response to therapy using imaging. Designees in MCW Radiology will perform measurements and calculate response using protocol-specified criteria (e.g., RECIST, ir-RECIST, Lugano, RANO, MacDonald, etc.).
- The MCWCC utilizes the clinical radiology services of Froedtert Hospital for imaging CT, MRI, PET, X-ray, DEXA, bone scans, digital mammography, etc.
  - The scanning parameters of each protocol are reviewed by the Froedtert Hospital clinical leads of each radiology modality. Our standard imaging protocols are defined for clinical care; research protocol requests are reviewed against the clinical routine care standard. If Froedtert can commit resources to a protocol request that is different from our routine care protocol, the work effort/costs are communicated to the MCW researcher. With those exceptions, research protocol imaging requirements are built and expectations are shared with the research team.
  - Requests for biopsies under an imaging modality (routine care vs. research-only) are reviewed using similar review analysis. For those requests that are not in line with the routine care workflow, the MCW researcher works collaboratively with the MCW Institutional Tissue Bank to facilitate based on each protocol requirement. Commitments/work effort/costs are shared with the MCW researcher.
  - Digital CT and MRI data are available in uncompressed DICOM format. The MCWCC works with the imaging data center at MCW’s Clinical & Translational Science Institute (CTSI) to acquire the image/data and send to sponsors/core imaging via secured websites. The CTSI provides image de-identification services.
- The MCWCC research study team is responsible for scheduling all imaging appointments, identifying any unique imaging requirements as defined by the Froedtert radiology lead review of the research protocol.

**CT**

- Froedtert Hospital has multi-detector helical scanners. Spiral and conventional CT can be performed without and/or with contrast.
- Froedtert Hospital utilizes a power injector for IV contrast.
- Slice thickness, spacing and reconstruction are dependent on many variables. The Froedtert Hospital Lead CT technologist reviews each research study to determine our ability to perform the image as requested. If the request is different from our routine care standard, a new protocol (see above) may be built and used at each research exam as necessary.
  - Due to the high volume of clinical patients scheduled on our scanners, research protocols cannot request that the same CT scanner be used for all the subjects.
MRI

- Froedtert Hospital has both 1.5T and 3.0T MRI scanners.
- Froedtert Hospital has an MRI-compatible power injector for IV contrast.
- Froedtert Hospital utilizes phased array coils.
- Slice thickness, spacing and reconstruction are dependent on many variables. The Froedtert Hospital Lead MRI technologist reviews each research study to determine our ability to perform the image as requested. If the request is different from our routine care standard, a new protocol (*see above) may be built and used at each research exam as necessary.
  o Due to the high volume of clinical patients scheduled on our scanners, research protocols cannot request that the same MRI scanner be used for all the subjects.

The MCWCC Research Manager will work through Froedtert Hospital’s OCRICC to collaborate with radiology staff for research project (study-specific) questions regarding imaging capabilities.

LABORATORY INFORMATION

| Cancer Center CTO Research Lab | • Refrigerator (2-8°C) as well as -20°C, -36°C, and -70°C freezers  
|                              | • Refrigerated and room temperature centrifuges  
|                              | • Vortex, water bath, pipettors  
|                              | • Access to dry ice, wet ice  
|                              | • Refrigerator and freezers are temperature monitored and alarm if they go out of range. They are backed up in case of power outage.  
|                              | • Our site has received IATA training in shipping biological or hazardous samples.  
|                              | • We routinely ship samples to central labs using FedEx, UPS, DHL, Marken, and World Courier; able to ship samples the day they are drawn. |

| Local Lab | Wisconsin Diagnostic Laboratories (formerly Dynacare)  
|          | 9200 W. Wisconsin Avenue  
|          | Milwaukee, WI 53226  
|          | Phone: 414-805-7600  
|          | Certifications and Accreditations: College of American Pathologists, American Association of Blood Banks, CLIA, Clinical Laboratory Permit-Pennsylvania Department of Health, Food and Drug Administration |
MEDICAL RECORDS and DATA/INFORMATION SYSTEMS

Computer Capability
- Each research staff member has a dedicated computer with high speed internet access.
- For security we have internal firewalls and virus software on all computers.
- High speed internet access – cable, broadband, wireless
- MCW IT support is available Mon-Fri 7am to 5pm, with limited support available after hours.
- We employ a clinical trial management system (OnCore), with electronic calendars and SAE/deviation monitoring capabilities

Source Data
- We utilize electronic medical records (Epic). This system includes laboratory reports, radiology reports, physician notes, procedure notes, etc.
- We have a CFR Title 21, Part 11 Attestation that electronic signatures in Epic are the legally binding equivalent of handwritten signatures, protected via user ID and password.
- An audit trail exists for all creation, deletion, and modification of electronic source data.
- Paper copies of source data are available as shadow charts. Limited access to Epic is available to monitors upon request.

Data Capture
- We have experience with multiple electronic data capture systems including OnCore, Medidata RAVE, IVRS, Open system, Phase Forward, Inform, Data Trak, Oracle Clinical Remote Data Capture, among others

Data Storage
- Secured to protect patient privacy
- All Regulatory and CRF study documents are held for a minimum of 10 years after study closure.
- Offsite archiving
  o Iron Mountain Storage, 5255 South International Drive, Cudahy WI 53110 and 5170 South 6th St., Milwaukee, WI 53187
  o C.H. Coakley & Company, 2151 North Dr. Martin Luther King Drive, Milwaukee, WI 53212

MONITORING VISITS

Meeting with Study Team
- We have designated space for monitor visits in the research office.
- Monitors have access to a printer and copier, as well as access to wireless internet.
- Monitoring visits must be arranged at least two weeks in advance. The study coordinator will facilitate identifying a date when required participants and space will be available. After the date is agreed upon, we must receive written notice of the visit at least two weeks prior to arrival, including a list of the required participants and the focus of the visit. Every effort will be made to have the study coordinator, PI, pharmacy and regulatory staff available for the visit if requested. Please note that if a monitor wants to review multiple studies during the same visit, we require two weeks advance notice for each study (i.e., studies cannot be reviewed impromptu).
• Subject shadow charts and regulatory binders are made available for monitors. Limited access to Epic can be arranged with two weeks advance notice.
• For additional information, please see our SOP regarding Monitoring visits located here: http://www.mcw.edu/cancercenter/Clinical-Trials-Office-/For-Research-Staff.htm

Visiting Investigational Pharmacy
• Investigational Pharmacy is available for monitor visits Mon-Fri 8:30am to 1:00pm.
• Monitors must contact the Pharmacy directly to set up a visit, and visits must be scheduled at least one week in advance. A maximum of three monitor visits per day is allowed, and visit requests are accommodated on a first come, first served basis.
• For each visit request, the Pharmacy needs to know the name of the study/studies the monitor needs to review, as well as an estimate of how much time a monitor anticipates spending at the pharmacy.

SOPs

Our Clinical Trials Office has written Standard Operating Procedures (SOPs) that include our policies on patient screening and enrollment, consenting, study monitor visits, and external safety reports.

Please access the current SOP versions here: http://www.mcw.edu/cancercenter/Clinical-Trials-Office-/For-Research-Staff.htm