Medical College of Wisconsin Cancer Center

Disease-Oriented Team Charter

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The Medical College of Wisconsin Cancer Center (MCWCC) has established Disease-Oriented Teams (DOTs) whose purpose is to serve as a forum to enhance coordination of patient care and clinical research. DOTs are disease- or discipline-specific groups composed of faculty from all relevant treatment modalities/disciplines, clinical staff, and research staff.

The DOTs and their chairs have responsibilities and functions divided among three areas: clinical research management, fostering of integrative research, and clinical service delivery and operations (service line). Service delivery/operations and integrative research will be touched on briefly here, but the purpose of this document is to describe the DOT clinical research function as the first stage of protocol review per the Protocol Review and Monitoring System section of the National Cancer Institute's Cancer Center Support Grant (CCSG) guidelines.

1. RESPONSIBILITIES

1.1 Clinical Research Management

A primary responsibility of each DOT is to actively manage a clinical trial portfolio that meets the needs of MCWCC's patient population and catchment area and advances the research goals of MCWCC.

Each DOT is expected to:

- Foster multidisciplinary collaborations among faculty that result in grants, investigator-initiated trials, and publications, as well as mentor junior investigators

- Design and implement investigator-initiated trials (IITs)
    - Identify opportunities for translation of MCW discoveries into clinical trials
    - Review initial study concepts/letters of intent for scientific merit and feasibility
    - Fairly and responsibly allocate philanthropic funds to investigator-initiated projects and help members identify external sources of funding

- Review new protocols for activation
    - Identify and review new trials for clinical and scientific merit, as well as alignment with DOT and MCWCC research goals
    - Evaluate the feasibility of new studies, including patient population availability and competition with existing trials, as well as trial complexity and impact on CTO resources
    - Hold formal votes on dispositions of new protocols to determine whether they will move forward in the activation process

- Assign prioritization scores to interventional trials
    - Prioritize new studies during initial review
    - Maintain a priority list that includes all pending interventional protocols in the portfolio
    - Maintain a protocol flow chart of all active and pending studies to visualize where new studies fit and identify competing trials

- Perform ongoing reviews of the DOT's research portfolio

    - Assess gaps in the current portfolio based on the patient population, and potential gaps given anticipated end dates of existing protocols
    - Review pending portfolio to resolve issues arising during the activation process
    - Review accrual rates to active trials, including by race/ethnicity/gender/age
    - Troubleshoot issues with underperforming trials, and close poorly accruing trials to ensure appropriate utilization of resources
    - Ensure that the overall portfolio optimizes the allocation of resources such as personnel, patient population, patient tissue/blood/data

- Develop and maintain a research portfolio that addresses the Cancer Center's mission of reducing cancer disparities in underserved populations.

- Maintain written records of all meetings, including attendance and decisions concerning accrual, prioritization, concept/protocol review.

1.2 Integrative Research

In addition to the clinical research management meetings, each DOT is encouraged to have Integrative Research meetings to foster the development of translational research. This activity is not part of the DOT's formal duties as the first stage of PRMS review. Rather, Integrative Research meetings are more informal and serve as a venue for clinicians and basic scientists to discuss their research and identify areas for collaboration.

1.3 Service Line Management

The Chairs of the adult clinic-based DOTs also have Froedtert service line responsibilities, which are outlined below. This section does not apply to the Pediatric or Population Sciences & Behavioral Health DOT Chairs. Adult service line responsibilities include the following:

- Establish and maintain high quality standards for the clinical practice particular to their disease focus.
    - Establish clinical quality measures for the DOT
    - Develop and implement plans to achieve health system quality measures in collaboration with inpatient teams
    - Monitor disease-based quality measures and develop plans to achieve targets and improve quality
    - Establish and achieve patient satisfaction targets

- Develop and implement plans to improve efficiency of patient care and reduce resource utilization
    - Develop and implement plans to improve efficiency and reduce cost of care for DOT patients in collaboration with Cancer Service Line
    - Conduct monthly meetings to establish clinical quality and value targets and implement plans to achieve and improve value metrics including length of stay, re-admissions, ED visits and other efficiencies.

- Participate in Clinical Operations meetings and provide input and decision-making in efforts to improve efficiency and effectiveness of clinical operations to improve patient care.

Please see the current DOT Chair job description for more information.

2. DISEASE-ORIENTED TEAM STRUCTURE

Every cancer study must be reviewed and approved by a DOT before it proceeds to the Scientific Review Committee (SRC). Most of MCWCC's DOTs are disease-specific, but a subset were established to specialize on a particular discipline or trial phase. Each protocol should have one DOT designated as the primary DOT responsible. In some cases, it may make sense for multiple DOTs to review a study (e.g., a Population Sciences & Behavioral Health study for breast cancer survivors may also be reviewed by the Breast DOT). In the rare case when a study doesn't have an obvious home DOT (e.g., a supportive care study open to any cancer), the Associate Director of Clinical Research will assign a DOT.

MCWCC Disease-Oriented Teams
Head and Neck
Thoracic
Sarcoma
Skin
Breast
Genitourinary
Gastrointestinal
Gynecology
Central Nervous System
Leukemia
Lymphoma
Plasma Cell Disorders
Bone Marrow Transplant/Cell Therapy
Adult Early Phase
Pediatrics
Population Sciences & Behavioral Health

2.1 DOT leadership

Each DOT is led by a physician Chair and Vice-Chair and includes a membership roster reflecting the relevant disciplines. The adult DOT Chairs and Vice-Chairs are selected by the MCWCC Associate Director of Cancer Clinical Operations (ADCCO), Associate Director of Translational Research (ADTR), and Associate Director for Clinical Research (ADCR), after consultation with clinical department and division leaders. For the Pediatric DOT, the Associate Director of Pediatrics and Survivorship (ADPS) will also be involved. Chairs are appointed to three-year terms with the possibility of a single renewal with exceptional performance. For implementation purposes, all chair terms will officially start as of 2023. Decisions regarding leadership changes within a DOT are the sole responsibility of the above associate directors. Faculty serving as a Chair or Vice-Chair of one DOT cannot simultaneously serve in either capacity on a second DOT, but they may be a voting member of multiple DOTs.

Chairs are selected based on their clinical research experience, dedication to clinical research and quality improvement, and proven track record. The Chair provides leadership and ensures the DOT is performing its functions effectively. Specifically, the Chair:

- leads the monthly DOT meetings, ensuring quorum is met
- provides mentorship to junior faculty
- attends monthly group DOT leadership meetings with the ADCCO, ADTR, and ADCR
- attends quarterly individual DOT leader meetings with the ADCCO, ADTR, and ADCR to align DOT research priorities and resources with MCWCC goals (the Population Science and Pediatric DOT Chairs meet with just the ADCR and ADTR)
- oversees the full portfolio of trials to ensure the goals of the DOT and MCWCC are met

The role of the Vice-Chair is to act as Chair when the Chair is absent or has a conflict of interest on a particular review item. Vice-Chairs have full signatory authority for decisions related to research activities. Vice-Chairs do not have decision-making authority over service line management- those duties reside with the DOT Chair role only.

2.2 Committee composition

The remaining DOT membership includes core voting members and non-voting members. Each DOT must maintain a roster listing their members and statuses (voting vs. non-voting).

Voting members consist of faculty investigators, both MDs and PhDs, as well as the CTO clinical research manager who supports that DOT. Each DOT should include voting representatives from all relevant modalities (e.g., medical oncology/hematology, radiation oncology, surgical oncology, interventional radiology, pathology, radiology, basic research) or disease-specific specialties (e.g., otolaryngology, urology) to ensure a multidisciplinary perspective. Additional faculty can participate as needed as ad hoc voting members. While scientific value and appropriateness for the patient population are best determined by faculty members, the CTO clinical research manager provides insight on study feasibility, such as logistical, staffing, and funding considerations.

Non-voting members, who are present at DOT meetings and participate in group discussions, may include the following:

- Other clinical staff involved in research (e.g., RNs, APNPs, PA-Cs, residents, fellows)
- Other CTO staff and departmental research coordinators

CTO staff support the administrative research operations of the DOTs. Clinical Research Managers coordinate with the Chair to set monthly meeting agendas, use OnCore to summarize and present clinical trial data, provide updates on pending protocols, and manage the disease team's trials throughout their life cycle. CTO staff are responsible for maintaining membership rosters for each DOT, recording meeting attendance, and recording meeting minutes and decisions.

DOT meeting attendance will be tracked. Voting members must attend at least 50% of DOT meetings or risk losing their voting rights.

3. DOT RESEARCH PORTFOLIO MEETINGS

(This section applies to the clinical research portfolio meetings only. The integrative research meetings are intended to be less formal.)

DOTs are expected to meet monthly (should meet at least 10 times per year).

A quorum of ≥50% of voting members is needed for DOT decisions. Quorum must include a Chair or Vice-Chair plus at least one representative from each of the modalities/disciplines relevant to the particular protocol(s) in question (e.g., if protocol requires surgery and radiation therapy, then at least one surgeon and radiation oncologist should weigh in). For decisions requiring a vote, only members present at the DOT meeting for the discussion either in person or virtually should count toward quorum and the vote. Emailed votes should not count toward quorum except in emergent situations, where a member is unexpectedly unable to attend the

meeting. DOTs may use emailed votes to reach quorum for no more than two meetings in a 12-month period.

All DOT decisions will be carried by a majority vote (i.e., decisions do not have to be unanimous).

Conflict of Interest

PIs and co-PIs are not allowed to vote on decisions made regarding their own investigator-initiated trials, as well as any externally sponsored trials for which they played a significant role in protocol development. PIs can vote on external trials for which their only involvement is as the site PI. Co-Is and Sub-Is are permitted to vote unless a significant conflict is identified. This applies to all decisions/reviews performed by the DOT (i.e., new concepts, new protocols, low accruing trials, etc.).

Chairs are prohibited from performing committee business on studies for which they are the PI. The Chair should defer to the Vice-Chair to conduct committee business for those studies, such as signing New Trial Submission Forms, etc. When the Vice-Chair is a PI, they should defer to the Chair.

In situations where most members of a DOT have a conflict of interest, the ADCR can review the study and make a determination.

3.1 New concept/protocol review

Per NCI guidelines, DOTs are responsible for the initial scientific review of concepts and full protocols. Investigator-initiated concepts and protocols, as well as external institutional, cooperative group, and industry-initiated trials are placed on DOT meeting agendas for group discussion. DOTs evaluate studies for scientific merit, potential for successful accrual, presence of competing protocols, and alignment with the academic goals of the disease group and MCWCC.

The vast majority of new studies approved by the DOT should go to full committee for review and a consensus decision. However, the DOT Chair can use their discretion to approve studies without committee input (e.g., a low-risk survey study or a study under a tight time constraint). Noninterventional studies may be approved by DOT Chairs offline. Offline approvals should be reported to the DOT at the next committee meeting.

Competing Studies

In general, competing studies should be avoided. When considering a new study, DOTs should review their list of active and pending studies. If the new study will compete with any existing studies, the DOT must determine whether the hospital has the patient population to support both studies and develop a plan for how the studies would be prioritized for enrollment.

Competing studies will be approved for activation under one of the following circumstances:

- the competing study is a slot-driven or multidisease early phase trial
- the active competing study demonstrates an adequate accrual rate and the patient population is large enough to support an additional study

- the active trial will complete accrual before the new trial is opened, or the DOT plans to close the current trial in favor of the new trial when it opens
- there are significant nonoverlapping eligibility criteria

Investigator-Initiated Trials

IITs are reviewed by the DOTs at two stages: concept and draft protocol. Investigators developing a potential study first bring the concept or LOI to the appropriate DOT for feedback. This is an important step intended to prevent faculty and staff from expending additional effort on projects with questionable scientific merit or limited interest to the DOT. It is an opportunity for the DOT to strengthen the proposed research through constructive feedback on the hypothesis, objectives, design, eligibility, etc. Concepts endorsed by the DOT can begin protocol development. Junior investigators should be mentored during trial development by either the DOT Chair or an assigned senior mentor. When drafting protocols, investigators have access to protocol templates provided by the CTO, as well as the services of the MCWCC medical writer. The study should come back to the DOT for review once there is a full protocol.

Review Outcomes

After discussion of each new concept or protocol, the DOT votes to assign one of the following outcomes:

- **Concept Approved** – Study concept merits pursuit.
- **Approved** – Full protocol has been reviewed. The study appears sound and fulfills a need in the current DOT research portfolio. The study may proceed to next step in activation process.
- **Approved Pending Clarification** – Full protocol has been reviewed. More information about some aspect is needed before approval can be given. Does not have to go back to full committee if issue resolves with additional information. Chair or Vice-Chair can approve.
- **Disapproval** – DOT declines to pursue or activate a concept or protocol for scientific or feasibility reasons.

Decisions are recorded in the meeting minutes. Most studies not pursued by DOTs are rejected because of competing trials or non-compelling science.

3.2 Review of pending/active portfolio

Each DOT should review its pending portfolio to monitor where studies are in the activation process and troubleshoot impediments to activation when possible.

DOTs are responsible for monitoring accrual to their active trials and taking appropriate action when underperforming studies are identified. At least quarterly, DOTs will review all enrolling studies for accrual progress, and discussions surrounding low-accruing trials, including reason(s) for low accrual, must be summarized in the meeting minutes. Trials that are zero-accruing for three months should be discussed for corrective action. To ensure optimal resource utilization, DOTs are strongly encouraged to close underperforming trials that are unlikely to improve. If the committee intends to keep the study open, then the DOT should formulate a corrective action plan and record this in the meeting minutes. Per NCI guidelines, the SRC has

ultimate authority to close low accruing trials and may overrule DOTs wishing to keep a trial open.

3.3 Inclusion of Women, Minorities, and All Age Groups

NCI expects that clinical trials will be made available to women, minorities, children (<18 years old), and older adults (>65 years old) unless there are clear scientific or ethical reasons not to include them. Accrual of these populations should be proportional to their representation in MCWCC's patient population/catchment area. The potential to accrue these populations should be discussed when considering each new trial, and the demographics of actual accrual to open trials should be reviewed at least quarterly. DOTs are responsible for identifying opportunities and strategies for recruitment and retention of these populations. DOTs should consider how new studies might contribute toward MCWCC's overall goal of reducing cancer disparities in our catchment area.

3.4 Protocol prioritization

Protocol prioritization is emphasized at the DOT level, where members have expertise in their respective areas, knowledge of the current research portfolio, and the best understanding of the clinical trial needs of the patients seen in their clinics. Along with science, DOTs must consider feasibility and logistics, resource allocation, and competing trials. As a rule, MCW IITs are higher priority than externally sponsored trials. Priority is also given to early phase studies providing access to cutting-edge treatments, studies with high accrual potential, and studies that may positively impact underserved populations in the catchment area.

When a new study is approved to move forward in the activation process, the DOT assigns it a prioritization score (see Appendix 1), which is reviewed by associate directors and the SRC. Scores are recorded as a data element in OnCore where they are accessible to DOTs and CTO staff. High-scoring studies receive higher priority for MCWCC and CTO resources.

4. COMMUNICATION WITH OTHER COMMITTEES

For new studies approved to move forward to the SRC, the DOTs must complete the New Trial Submission Form and a Prioritization Scoresheet. The DOT Chair's signature on the New Trial Submission Form attests that the DOT has reviewed the accompanying protocol and supports its activation.

DOTs, either through the Chair, PI, or both, are responsible for responding to all queries or concerns raised by the Protocol Feasibility Review Committee, SRC, and Data and Safety Monitoring Committee regarding review of new or ongoing studies.

5. OVERSIGHT OF DOT ACTIVITIES

The SRC provides oversight over DOT decisions regarding activation of new protocols and disposition of low accruing studies. The ADCCO, ADTR, ADCR, and ADPS meet with DOT Chairs, review portfolios, and provide direction and feedback. Lastly, DOTs are subject to review by the MCWCC Clinical Research Executive Committee (CREC) to ensure compliance

with MCWCC DOT policies for research. Chaired by the ADCR, CREC has the authority to impose corrective action if a committee does not satisfactorily carry out its responsibilities.

Appendix 1.

Adult Protocol Prioritization Scoresheet

Evaluation Factor	Categories	Points	Earned
Funding Source/Sponsor	NIH-funded IIT/NCTN trial with MCW PI	6	
	Institutionally funded interventional IIT	5	
	Industry-funded IIT	3	
	NCTN or BMT CTN trial	2	
	Industry trial	1	
	External Institutional/Consortium Trial	1	
Clinical/Scientific Impact	Likely to be a breakthrough drug/treatment modality	4	
	Phase I first in class/FIH having potential impact across multiple tumor types/preclinical data support	3	
	Phase I-III trial with possible practice changing implications	2	
	Phase I-III trial with few practice changing implications	1	
	Post-marketing study	0	
Annual Accrual Potential	>10	4	
	5-10	2	
Competing Trials	No competing trials (same eligibility/similar mechanism) open or pending	1	
Academic Value	First/Last authorship	3	
	Middle authorship	1	
Local PI is junior investigator (<5 yrs out from fellowship)	Yes	1	
MCW Lab Correlates (Hypothesis-driven)	Yes	3	
Uniquely Addresses Underserved Populations in Catchment Area	Yes	3	
Alignment with MCWCC Strategic Goals (scored by Feasibility Committee)		0-3	
		Total:	

Clinical/strategic importance of this study to the DOT:

Pediatric Protocol Prioritization Scoresheet

Variable	Options	Score
Funding Source	NCI/NIH	10
	External Grant	10
	Industry	6
	MACC/Internal Funds	4
	Non-funded	0
Funding Level	Fully-Funded	10
	Partially-Funded	5
	Non-Funded	0
Investigator-Initiated Trial?	Yes	10
	No	0
Authorship	Yes	5
	No	0
Scientific Value	Cell, Gene, or Immune Therapy	10
	Phase I / II	8
	Phase III	6
	Non-Therapeutics	6
	Biology	4
	Chart Review	2
	QI Project	0
Accrual Potential (annualized)	5 or more	10
	2-5	5
	1 or fewer	0
Strategic Priority	High	10
	Medium	5
	Low	0
Clinical Need	High	10
	Medium	5
	Low	0
Resource Utilization	High	0
	Medium	5
	Low	10