Medical College of Wisconsin Cancer Center

Integrated Disease-Oriented Team Charter

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

The iDOTs and their chairs have responsibilities and functions divided among three areas: clinical trial management, fostering translational research, and clinical service delivery and operations (service line). Service delivery/operations and translational research will be touched on briefly here, but the primary purpose of this document is to describe the iDOT 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.

The iDOTs are overseen by the MCWCC Associate Director of Clinical Research (ADCR), the Assistant Director of Clinical Research (AsstDCR), and the Associate Director of Oncology Operations (ADOO). Additionally, the Assistant Director of Clinical Research for Clinical Trial Access oversees iDOT performance related to serving all populations in the catchment area.

1.0 Responsibilities

1.1 Clinical Research Management

A primary responsibility of each iDOT 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 iDOT 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
    - Assist members with identifying internal and external sources of funding
- Review new protocols for activation
    - Identify and review new trials for clinical and scientific merit, as well as alignment with iDOT 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 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 gaps in the portfolio and determine where new studies fit and identify competing trials
- Perform ongoing reviews of the iDOT'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, assessing progress toward accrual goals and access to patients throughout the catchment area
    - 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
- 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 Integrated Science Meetings

In addition to the clinical research management meetings, each iDOT is encouraged to have Integrated Science Meetings to foster the development of translational research. Integrated Science Meetings provide informal venues for clinicians and basic and population scientists to discuss their research interests and brainstorm about areas for collaboration. Meetings range from those focusing on single diseases (e.g., pancreas cancer) within an iDOT to thematic topics that cross iDOTs (e.g., immuno-oncology). These meetings are not part of the iDOT's formal duties as the first stage of PRMS review but are meant to facilitate team science that leads to translational, bench-to-bedside research.

1.3 Service Line Management

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

2.0 Integrated Disease-Oriented Team Structure

Every cancer trial must be reviewed and approved by an iDOT (**Table 1**) before it proceeds to the Scientific Review Committee (SRC). Most of MCWCC's iDOTs are disease-specific, but a subset specialize in a particular discipline or trial phase. Each protocol has one iDOT designated as the primary responsible iDOT. In some cases, it may make sense for multiple iDOTs to review a study (e.g., a Population Sciences & Behavioral Health study for breast cancer survivors may also be reviewed by the Breast iDOT). In the rare case when a study doesn't have an obvious home iDOT (e.g., a supportive care study open to any cancer), the ADCR will assign an iDOT.

2.1 DOT leadership

Each iDOT is led by a physician Chair and Vice-Chair and includes a membership roster reflecting relevant disciplines. Faculty serving as a Chair or Vice-Chair of one iDOT cannot simultaneously serve in either capacity on a second iDOT, but they may be a voting member of multiple iDOTs. The ADCR recommends selection of adult iDOT Chairs to the Cancer Center Director after evaluation of nominees by the ADCR, the AsstDCRs, and ADOO, and consultation with clinical department and division/section leaders. The Director appoints Chairs to three-year, renewable terms. Decisions regarding leadership changes within an iDOT are the sole responsibility of the above associate directors.

Table 1. Integrated 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

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 iDOT is performing its functions effectively. Specifically, the Chair:

- leads the monthly iDOT meetings, ensuring quorum is met
- provides mentorship to junior faculty
- attends monthly group iDOT leadership meetings with the ADOO, ADCR, and AsstDCRs
- attends quarterly individual iDOT leader meetings with the ADCR, AsstDCR and ADOO to align iDOT research priorities and resources with MCWCC goals
- oversees the full portfolio of trials to ensure the goals of the iDOT and MCWCC are met

Vice-Chairs are nominated by the Chairs. Vice-Chair nominations are considered by the ADCR, AsstDCRs and ADOO who recommend appointments to the Cancer Center Director. 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 iDOT Chair role only.

2.2 Committee composition

The remaining iDOT membership includes core voting members and non-voting members. Each iDOT 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 iDOT. Each iDOT 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 iDOT 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 and research operations of the iDOTs. 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 team's trials throughout their life cycle. CTO staff are responsible for maintaining membership rosters for each iDOT, recording meeting attendance, and recording meeting minutes and decisions.

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

3.0 iDOT Research Portfolio Meetings

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

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

A quorum of ≥50% of voting members is needed for iDOT 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 iDOT 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. iDOTs may use emailed votes to reach quorum for no more than two meetings in a 12-month period.

All iDOT 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 iDOT (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 an iDOT have a conflict of interest, the ADCR or AsstDCR can review the study and make a determination.

3.1 New concept/protocol review

Per NCI guidelines, iDOTs 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 iDOT meeting agendas for group discussion. iDOTs 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 majority of new studies considered by the iDOT should go to full committee for review and a consensus decision. However, the iDOT Chair can use their discretion to give expedited approval for studies without committee input (e.g., low-risk noninterventional studies). Expedited approvals should be reported to the iDOT at the next committee meeting.

Adult cellular therapy trials: Cellular therapy trials (both solid tumor and hematologic malignancy) require involvement of both the relevant disease-specific iDOT and the Bone Marrow Transplant/Cell Therapy (BMT/CT) iDOT. The disease-specific iDOT is responsible for full review to evaluate scientific value, trial portfolio fit, prioritization, etc. and makes the decision whether to advance the trial for activation. For BMT/CT iDOT review, in most circumstances, the chair (or vice chair in case of a conflict) will perform an electronic expedited review, approving the trial for SRC submission without a formal BMT/CT iDOT vote. In rare cases,

the BMT/CT iDOT chair may ask for full BMT/CT iDOT review (e.g., studies with unusual or complex logistics) before clearing the study for SRC submission. BMT/CT iDOT review can be concurrent with the originating iDOT's review. All cell therapy trials should be presented at a BMT/CT iDOT meeting for committee awareness, but this step can occur after SRC submission for studies administratively approved by the BMT/CT iDOT chair.

Competing Studies

In general, competing studies should be avoided. When considering a new study, iDOTs should review their list of active and pending studies. If the new study will compete with any existing studies, the iDOT must determine whether the institution has the patient population to support both studies and develop a triage plan for which patient subpopulation would be prioritized for enrollment to which study based on the trials' specific eligibility criteria and type of therapy.

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

- the competing study is a slot-driven or multi-disease 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 iDOT 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 iDOTs at two stages: concept and draft protocol. Investigators developing a potential study first bring the concept or LOI to the appropriate iDOT 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 iDOT. It is an opportunity for the iDOT to strengthen the proposed research through constructive feedback on the hypothesis, objectives, design, eligibility, etc. Concepts endorsed by the iDOT can begin protocol development. Junior investigators should be mentored during trial development by either the iDOT Chair or an assigned senior mentor and encouraged to present their concept to the MCWCC IIT Steering Committee (IITSC). The IITSC can also provide protocol development mentoring. When drafting protocols, investigators have access to protocol templates provided by the CTO, as well as the services of the MCWCC Research Development Office. Studies should come back to the iDOT for review once there is a full protocol. As of April 2025, treatment protocols must also be submitted, either before or concurrently with iDOT review, to the IIT Steering Committee for review, to ensure quality products move forward to the FDA and SRC.

Review Outcomes

After discussion of each new concept or protocol, the iDOT 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 iDOT 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.
- **Disapproved/Declined** – iDOT declines to pursue or activate a concept or protocol for scientific or feasibility reasons.

Decisions are recorded in the meeting minutes.

3.2 Review of pending/active portfolio

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

iDOTs are responsible for monitoring accrual to their active trials and taking appropriate action when underperforming studies are identified. iDOTs should review all enrolling studies for accrual progress at least quarterly, 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, iDOTs are strongly encouraged to close underperforming trials that are unlikely to improve. If the committee intends to keep the study open, then the iDOT 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 iDOTs decision to keep a trial open.

3.3 Serving the Catchment Area

NCI expects that clinical trials be accessible to all persons in the catchment area, regardless of sex, race, ethnicity, age or geography. Accrual of demographic subpopulations 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. iDOTs are responsible for identifying opportunities and strategies for recruitment and retention of under-enrolling populations. iDOTs 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 iDOT 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, iDOTs 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 iDOT assigns it a prioritization score (see Appendix 1), which is reviewed by the Feasibility Committee and the SRC. Scores are recorded as a data element in OnCore where they are accessible to iDOTs and CTO staff. High-scoring studies receive higher priority for MCWCC and CTO resources.

4.0 Communication with Other Committees

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

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

5.0 Oversight of iDOT Activities

The Feasibility Committees and SRC provide oversight over iDOT decisions regarding activation of new protocols and disposition of low accruing studies. The ADCR, AsstDCR, and ADOO meet with iDOT Chairs, review portfolios, and provide direction and feedback. Lastly, iDOTs are subject to review by the MCWCC Clinical Research Executive Committee (CREC) to ensure compliance with MCWCC iDOT 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.

Protocol Prioritization Scoresheet

Evaluation Factor	Categories	Points	Earned
Sponsor/Funding Source	NIH-funded IIT/NCTN trial with MCW national PI	6	
	IIT funded by a grant (non-NIH), industry, or institutional source	5	
	NCTN or BMT CTN trial	3	
	External cancer center, non-NCTN consortium	2	
	Industry trial	1	
Annual Accrual Potential	Adult: ≥11; Pediatric: ≥5	4	
	Adult: 5-10; Pediatric: 2-4	2	
Academic Value	First/Last authorship	3	
	Second, second-to-last authorship	2	
	Middle authorship	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/unique pediatric access to a therapeutic	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	
Competing Trials	No competing trials (same eligibility/similar mechanism) open or pending	1	
Local PI is junior investigator (<5 yrs out from fellowship)	Yes	1	
MCW Lab Correlates (Hypothesis-driven)	Yes	3	
Uniquely Addresses Populations in Catchment Area	Yes	3	
Alignment with MCWCC Strategic Goals (scored by Feasibility Committee)		0-6	
		Total:	

Clinical/strategic importance of this study to the iDOT: