University of Illinois Cancer Center
Disease Team Policies & Procedures

1. Definitions

ADCR	Associate Director of Clinical Research
CCSG	Cancer Center Support Grant
Patient-Oriented Clinical Research	This type of research is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual, tissue banking, and studies that do not require patient consent (e.g., retrospective chart reviews). Patient-oriented research includes: o Studies of mechanisms of human disease o Studies of therapies or interventions for disease o Clinical trials, and o Studies to develop new technology related to disease
CTO	Clinical Trials Office
PI	Principal Investigator
PRC	Protocol Review Committee
PRMS	Protocol Review and Monitoring System
UICC	University of Illinois Cancer Center

2. Introduction

This policy outlines required conduct for UICC disease team meetings. Disease teams are expected components of the PRMS within NCI-designated cancer centers. They are important for the cancer center in ensuring that studies are vetted for: (1) appropriateness given the UICC patient population and the current study portfolio (i.e., to ensure no overlapping studies), (2) clinical operational feasibility for activation and implementation, and (3) meeting UICC's clinical research priorities. Disease teams are also responsible for continuous evaluation of low accruing studies to determine the potential for closure. Cancer-related, hypothesis-driven, patient-oriented clinical research studies conducted by the UICC must be reviewed and approved by an appropriate disease team, or the CTO Medical Director should an applicable disease team not be constituted, prior to PRC and IRB review. In addition, all studies conducted in UI Health Oncology clinical settings will be reviewed by a relevant disease team, regardless of cancer relevance, to assure that oncology clinicians are aware of the study and that the study does not present operational barriers or portfolio overlaps. Cancer relevant studies are evaluated for continuation at each meeting.

3. Responsible Personnel

- ADCR
- CTO Medical Director
- Disease Team Coordinator
- Disease Team Leader
- Disease Team Members
- PI

- Study Activation Specialist

4. Procedures

4.1. Disease Team Composition

Disease teams will be organized around a disease group (e.g., hematological malignancies), a logical combination of disease groups (e.g., women's cancers, GU cancers), or a type of cancer trial design (e.g., Phase I) as is appropriate for the clinical context of the institution. Disease team groupings will change over time to meet the needs of the institution. Disease teams will be comprised of all relevant personnel to provide comprehensive input into the decisions required of disease teams (see below). At a minimum, they will be comprised of investigators, treating physicians, clinical and research nurses, clinical research coordinators, investigational drug service, laboratory staff, and other clinicians when applicable (i.e., radiologists, pathologists). Disease teams may invite ad hoc members to assist with reviewing studies where additional expertise is needed. Disease teams will be led by Disease Team Leaders, who are appointed by and report to the ADCR, and whose responsibilities include approving meeting agendas, leading the meetings (see below), and approving the minutes of the meetings.

4.2. Disease Team Meetings

4.2.1. Meeting Timing

Disease team meetings will be held at a frequency sufficient to review the studies assigned to it per the requirements set forth below, usually once per month for an hour.

4.2.2. Meeting Conduct

Disease team meetings will be held at a regular time convenient for most members. They will be coordinated by a Disease Team Coordinator, usually a CTO Regulatory Specialist responsible for the regulatory submissions for that disease site. Meetings will be led by Disease Team Leaders. Meetings will be conducted according to a standard format and decisions will be documented in minutes (see below) reviewed and approved by the Disease Team Leader. If sufficient disease team members are not available to appropriately review the studies on the agenda, all agenda items requiring a vote will be rolled over to the next meeting. If there is not appropriate clinical representation to review the issue, or waiting for the next team meeting would significantly delay a time sensitive study, the item can be distributed to the appropriate members for consideration by email and reviewed by the Disease Team Leader. The outcome of the email deliberation will be reported at the next meeting and documented in the meeting minutes.

Studies will be assigned to disease teams based upon the disease site being studied. Studies involving multiple disease sites may be assigned to disease team for a vote based on most prevalent disease site, first available applicable disease team meeting, or relevant trial design (phase 1, cell therapy, etc.), and then will be taken to all related disease team meetings for information and to confirm feasibility. The meeting agenda and any potential studies for consideration during the meeting will be approved by the Disease Team Leader and distributed to the disease team members prior to the meeting.

4.2.3. Meeting Format

Disease team meetings will be conducted in a standardized way utilizing a standard agenda

prepared by the Disease Team Coordinator (see agenda template in Attachment A). The items requiring discussion in disease team meetings are described below. The meeting is also a forum to communicate additional study related information such as important protocol updates and amendments, as well as accrual updates.

4.2.3.1. New Studies

All new cancer-related, hypothesis-driven clinical research studies conducted at UICC must be reviewed by a Disease Team if one has been constituted. Studies are submitted for consideration by being emailed to the Disease Team Coordinator for the disease team. The disease team coordinator will distribute any new studies for consideration in advance of the meeting. Studies will be presented to the disease team by the study PI or a delegate. The disease team will review the following aspects of the study:

- Faculty interest and capability
- Appropriate for the patient population
- Implementation feasibility
- Overlap with ongoing studies
- Fit within UICC priorities

All new studies will be reviewed against the study flowchart for the disease group which shows the current activated studies in relation to disease type/stage. After the study is discussed, a vote will be taken to approve or disapprove the study to move forward to PRC review. Decisions will be made by the majority of those present at the meeting and will be noted in the meeting minutes. The PRC will not review studies disapproved by the disease team. Studies Disease Team protocol decisions will be tracked centrally.

4.2.3.2.Studies Being Activated

The status of all disease site-related studies in the activation phase will be reviewed in the associated disease team meeting to update the clinicians and allow them to ask questions about the studies.

4.2.3.3.Studies Open to Accrual

All studies open to enrollment involving the disease team will be presented. Information presented will include enrollment numbers at UICC and study wide. Potential subjects identified, enrollment barriers, and studies failing to enroll will be discussed. Studies that have failed to enroll will be reviewed to determine whether the studies should continue to remain open. If it is decided that a study should be closed, and the study PI is not present at the meeting, the PI will be asked to attend the next convened meeting of the disease team to discuss the decision to close the study. All decisions with their rationale will be documented in the meeting minutes. Should the PI not agree with the closure decision, the minutes containing the Disease Team recommendation to close the study will be forwarded to the PRC for consideration. A Disease Team does not have the authority to close a study. Only the PI, the PRC, and the IRB can close a study.

4.2.4. Meeting Documentation

All decisions and action items will be documented by the Disease Team Coordinator in the minutes derived from the agenda developed for the meeting. The minutes will be completed and distributed by the Disease Team Coordinator to disease team members and any other attendees of the meeting, such as non-disease team member faculty presenting their study at the meeting, within one week of the meeting. Studies approved for implementation by the

disease team will be submitted to the PRC with a copy of the disease team meeting minutes approving the study.

5. Related Policy
SSU01-1 Investigator and Sponsor Feasibility

6. Collaboration
This policy was developed in collaboration with the following departments: UICC and CTO

7. Attachments
A. Disease Team Meeting Agenda Template

Author
Annette Kinsella, QA Education Specialist

Associate Director, Clinical Research

Approval Signature:_____ Date: _____

ATTACHMENT A

Disease Team Meeting Agenda Template

University of Illinois Cancer Center
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Author
Annette Kinsella, QA Education Specialist

Associate Director, Clinical Research

Approval Signature:_____ Date: _____

ATTACHMENT A

Disease Team Meeting Agenda Template

University of Illinois Cancer Center
Disease Team Meeting

Agenda

Day, Month XX, 20XX
Location

☒ Present	☐	☐	☐	☐
☐ Excused	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	

1) Trials for consideration

Protocol Number	Sponsor	Protocol Title	Possible PI	Priority Score[i]	Expected Pts/Year	Enrollment Period	Enrollment Barriers?	Screen Failure Ratio	Competing Studies?	Pursue Study?	Notes

2) Studies in activation process

3) Studies open to accrual

4) Reminders/ Annoucments

- Next meeting Date XX-MMM-YYYY

5) Other Items for Discussion

i

Study Originator	Study Type	Score
IIT	Treatment	1
NCTN	Treatment	2
Foundation or External IIT	Treatment	3
Industry	Treatment	4
IIT	Interventional	5
NCTN	Interventional	6
Foundation or External IIT	Interventional	7
Industry	Interventional	8
NCTN	Non-interventional	9
IIT	Non-interventional	10
Foundation or External IIT	Non-interventional	11
Industry	Non-interventional	12