Robert H. Lurie Comprehensive Cancer Center Research Oversight System

Disease Team Charter

Overview

The Robert H. Lurie Comprehensive Cancer Center of Northwestern University (RHLCCC) has an integrated system for the review of cancer-focused clinical trials. This system relies on the coordination of committees to ensure all trials receive appropriate consideration in the areas of scientific importance as defined by the RHLCCC and the Disease Teams. The committees work together to provide a complementary review, but each has a distinct, and clearly defined role. The result of the various reviews is that each clinical trial is evaluated for its alignment with RHLCCC overarching objectives. The likelihood of successful completion of each trial is maximized through an assessment of its feasibility, priority in the context of potentially competing trials, and scientific integrity.

The committees involved in protocol assessment include:

- *Disease Teams:* the Disease Teams are a component of the RHLCCC Clinical Science Research Programs, thus are a critical part of the Research Oversight System. The Disease Teams are primarily responsible for review of new and ongoing studies to ensure alignment with the clinical/scientific mission, adequate commitment of the team, feasibility, team priority, and timely accrual.
- *Scientific Review Committee (SRC):* The SRC is ultimately responsible for evaluating new and ongoing clinical research protocols for scientific merit, institutional objectives/overall priority, and ongoing progress.

Disease Team Purpose

The primary objective of each Disease Team is to provide an integrated, multidisciplinary approach to guide the selection and endorsement of high quality cancer clinical trials. Each Disease Team is charged with establishing priorities within the framework described below.

To meet these objectives, the Disease Teams and their members are responsible for the following:

- Collaborating to develop areas of research with potential impact in the field of study

- Reviewing initial study concepts/letters of intent (LOIs) for NU investigator-initiated trials;
- Review and endorsement of all new trials which are to be opened
- Ongoing review and prioritization of interventional studies
- Performing ongoing review of the Disease Team's research portfolio, including a review of accrual rates for existing trials
- Optimizing population subgroup recruitment, including increasing both gender and racial/ethnic diversity
- Maintaining a priority list of pending and active protocols for their research portfolio

Disease Team Structure

Disease Teams have been formed for each established program within the RHLCCC Clinical Sciences Research Division. The list of Disease Teams, along with each team leader and co-leader, is found online at http://cancer.northwestern.edu/ROS/diseaseteam.cfm.

Membership Selection

The RHLCCC Deputy Director is responsible for approval of the formation of Disease Teams. Each Disease Team is led by a physician and includes a multidisciplinary membership roster. The Disease Team Leaders and Co-leaders are appointed by the Deputy Director, with terms lasting three years, renewable upon Deputy Director's reapproval. The remaining membership consists of disease-focused members and may include:

- Investigators (MDs and PhDs) - *voting members*
- Other clinical staff involved in the research (e.g. research nurses) – *non-voting attendees*
- Clinical Trials Office staff – *non-voting attendees*
- Clinical Research Administrators – *non-voting attendees*

To ensure a multidisciplinary perspective, the Disease Team composition includes a breadth in discipline, including, but not limited to personnel from the following departments (as appropriate): Medical Oncology/Hematology, Pathology, Radiation Oncology, Radiology, Interventional Radiology, Laboratory Research, and Surgery. Disease Team membership rosters are maintained by the Disease Team Program Coordinator.

Disease Teams are required to meet at least monthly to review new project proposals and the full portfolio of trials. A quorum is required for the conduct of every Disease Team meeting, defined as 50 percent of the Disease Team membership roster. Trials may be reviewed on an ad hoc basis between meetings as is necessary based on their priority.

Meeting Agenda

LOI Review for NU Investigator-Initiated Trials (IITs)
At the RHLCCC, the review of NU investigator initiated clinical trials is a two-step process, including review of a Letter of Intent (LOI) followed by review of the full protocol for LOIs which are endorsed. LOI review is an important step intended to reduce faculty and staff effort in developing protocols of lesser scientific merit or redundancies; therefore, investigators must first submit NU IIT LOIs to the Disease Team for review. This review provides an opportunity for the Disease Team to strengthen the proposed research by offering constructive feedback on the hypothesis, objectives, research design concepts, eligibility criteria, etc. LOIs that are determined to be of scientific importance to the Disease Team, that do not overlap with existing trials, and those which can reasonably be expected to complete accrual within the desired time frame, may be endorsed and begin protocol development.

Protocol Endorsement
The Disease Teams review potential protocols for endorsement, taking into account their overall study portfolio, potential competing studies, patient population, and likelihood of successfully accruing patients to the trial. The Endorsement Form is completed and signed by the Disease Team Leader or Co-Leader and is made available to the SRC at the time of submission. With the endorsement of the protocol, a table/figure with the new study prioritized within the overall team's portfolio of trials, must be submitted to the SRC.

Prioritization of Potential Trials
Each Disease Team reviews a list of active clinical trials to determine whether the proposed study competes with an existing trial. If a study is deemed to be in competition with an ongoing study, the Disease Team must determine whether:

1) current accrual rates based on the annual accrual goal and the institution's patient population justify keeping both studies open or
2) If any competing study or studies should be closed or are expected to close before the new trial is opened

Multiple competing studies are not allowed, with the exception of the following:

- early phase studies
- competing studies demonstrate adequate accrual rates and/or are anticipated to complete accrual before the new trial is opened or do not completely overlap
- There some non overlapping eligibility criteria

Adequate accrual rates vary depending on the target accrual for each trial. When a Disease Team determines that it is acceptable to have competing late phase studies open, it should establish a prioritization rule for subject accrual to those competing studies: in general, the highest priority should be given to IITs.

Inclusion of Women and Minorities or Population Subgroup Recruitment
It is expected that women and members of minority groups and their sub-populations be included in all RHLCCC clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Accrual of women and minorities to interventional therapeutic, interventional non-therapeutic and non-interventional studies should be proportional to the patient population in the Lurie Cancer Center's primary catchment area. Disease Teams are responsible for identifying opportunities and strategies for recruitment and retention of women and minorities; periodic review of recruitment rates for women and minorities will be conducted to correct any deficiencies that are noted.

Regular Review of Research Portfolio and Trial Accrual
Disease Teams are responsible for ongoing review of accrual to their active trials. The Disease Teams regularly discuss protocols that are not accruing as expected and preemptively make recommendations to address accrual issues.

Communication with other committees of the Research Oversight System
The Disease Teams are responsible for providing a coordinated response to any questions or concerns raised by the other committees of the Research Oversight System, including the SRC, the Data Monitoring Committee (DMC) and the Clinical Trial Audit Committee (CTAC) as is appropriate or warranted.

Responsibilities of the Lead/Co-lead

Each Disease Team Leader/Co-leader is responsible for ensuring the Disease Team functions effectively as outlined in this Charter. Specifically, they:

- Chair each Team meeting, and ensure quorum is met
- Facilitate any ad hoc meetings or communications (i.e., by email or teleconference) as needed
- Provide mentorship to junior faculty in the Team, one key goal being the development of IITs
- Arbitrate discussions regarding priority of trials
- Oversee the full portfolio of trials to ensure the goals of the Cancer Center are met (portfolio includes industry, IITs, and NCTN trials and emphasis on minority accrual)

Responsibilities of the Disease Team Program Coordinator

- The Disease Team Program Coordinator is responsible for: Maintain membership rosters for Disease Teams
- Create and distribute agendas and materials to the Disease Team for review;
- Record meeting attendance
- Prepare and route Disease Team outcomes (including endorsements, disapprovals, and voluntary study closure decisions) to the SRC and other committees as needed;
- Record and maintain Disease Team minutes
- Maintain priority lists for workflow and patient accrual based on disease team discussions

Interaction with Robert H. Lurie Comprehensive Cancer Center Leadership and Committees

Cancer Center Senior Deputy Director

The Deputy Director supervises the Lurie Cancer Center's Research Oversight System including providing oversight of the Lurie Cancer Center Research Oversight Committees, which includes the SRC, DMC and CTAC. These are independent committees responsible for scientific review, ongoing monitoring, and quality control/review of clinical trials.

SRC

Disease Team endorsement forms and prioritization lists are made available to the SRC for review. The SRC will consult the Disease Team's Priority List at the time it reviews new and ongoing research. If the SRC disagrees with the prioritization of a new protocol, this is communicated to the Disease Team leaders and Program Coordinator for discussion at the next Disease Team meeting.