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# Data and Safety Monitoring Plan

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## Abbreviations

AER	Adverse Event Report
CAPA	Corrective and Preventative Action Plan
CFR	Code of Federal Regulations
COI	Conflict of Interest
CTAC	Clinical Trial Audit Committee
CTEP	Cancer Therapy Evaluation Program
CTEP AERS	CTEP Adverse Event Reporting System
CTO	Lurie Cancer Center Clinical Trials Office
DCTD	Division of Cancer Treatment and Diagnosis
DCP	Division of Cancer Prevention
DT	Disease Team
DLT	Dose-limiting Toxicity
DSMC	Data and Safety Monitoring Committee
DSMB	Data and Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
eCRF	Electronic Case Report Form
FDA	Food and Drug Administration
FIH	First in Human
FSM	Feinberg School of Medicine
HIPAA	Health Insurance Portability and Accountability Act
IDE	Investigational Device Exemption
IIT	Investigator-Initiated Trial
IND	Investigational New Drug
IRB	Institutional Review Board
JBVAMC	Jesse Brown VA Medical Center
LCC IIT	Lurie Cancer Center Investigator-Initiated Trial
LCH	Ann & Robert H. Lurie Children's Hospital of Chicago
LOI	Letter of Intent
NCI	National Cancer Institute
NIH	National Institutes of Health
NOTIS	Northwestern Oncology Trial Information System
NU	Northwestern University
PI	Principal Investigator
QA	Quality Assurance
QAM	Quality Assurance Monitor
RNI	Reportable New Information
ROS	Research Oversight System
SAE	Serious Adverse Event
SFI	Significant Financial Interests
SIM	Study Implementation Meeting
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
SRAL	Shirley Ryan Ability Lab
SRC	Scientific Review Committee
SUSAR	Suspected Unexpected Serious Adverse Reaction
UPIRSO	Unanticipated Problems Involving Risks to Subjects or Others
VAERS	Vaccine Adverse Events Reporting System

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\* Please note: through this document, all references to online documents can be found on the Lurie Cancer Center website at <https://www.cancer.northwestern.edu/research/clinical-trials-office/research-oversight.html>

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# Data and Safety Monitoring Plan

## 1.0 INTRODUCTION

The Robert H. Lurie Comprehensive Cancer Center (Lurie Cancer Center) of Northwestern University (NU) has a diverse research program, including a large portfolio of protocols in the areas of primary cancer treatment and prevention, cancer control and other interventional trials, observational and outcomes studies, and lab-based research including correlative and ancillary studies. Therapeutic trials range from First in Human (FIH) and Phase I trials to multi-institutional randomized Phase III studies. The Lurie Cancer Center is dedicated to ensuring that all clinical trials are appropriately monitored to ensure research participant safety and that the validity and integrity of clinical trial data are maintained. Responsibility for this mission falls to the committees that comprise our Research Oversight System (ROS).

The Lurie Cancer Center's Data and Safety Monitoring Plan (DSMP) has been developed to provide oversight for data and safety monitoring for clinical trials consistent with the following: the *NIH Policy for Data and Safety Monitoring* as of June 10, 1998; *Policy of the NCI for Data and Safety Monitoring of Clinical Trials* as of June 22, 1999; *Further Guidelines on a Data and Safety Monitoring Plan for Phase I and II Trials* from the NIH on June 5, 2000; *Essential Elements of a Data and Safety Monitoring Plan for Clinical Trials Funded by the NCI* as of April 2001; and The Cancer Centers Branch of the National Cancer Institute Parts I and II: Policies and Guidelines Relating to the Cancer Center Support Grant, dated September 2004. This document provides a description of the Lurie Cancer Center's policies and procedures related to data and safety monitoring activities at the center.

## 2.0 BACKGROUND

### 2.1 Definition of a Clinical Trial

This plan follows the NIH definition of a clinical trial, released October 23, 2014 that states a clinical trial is "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." Interventions may include drugs, treatments, devices, or behavioral or nutritional strategies. Participants in these trials may be patients with cancer or people without a present diagnosis of cancer, but who are considered cured from a prior cancer and/or people who are considered to be at risk for developing it in the future.

Diagnostic research utilizing molecular or imaging diagnostics is considered to be a clinical trial if the information from the diagnostic test is used in a manner that affects medical decision-making for the study participant. As such, the information from the diagnostic test may have an impact on some aspect of outcome, and assessment of this impact may be a key goal of the trial. Studies that do not use information from the diagnostic test in a manner that can affect the outcome of study participants, but whose objective is solely the gathering of data on the characteristics of a new diagnostic approach, are not clinical trials and are not covered by this policy (unless performing the diagnostic test itself imposes some risk on study participants).

Behavioral clinical trials include interventions whose goals are to increase behaviors (e.g., cancer screening, physical activity, etc.), eliminate or reduce behaviors (e.g., smoking, sun exposure) and/or improve coping and quality of life and reduce the morbidity associated with treatment. Interventions may pertain to cancer prevention, early detection, treatment, and survivorship.

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Observational studies and those that do not test interventions are not considered clinical trials.

## 2.2 Applicability

This plan applies to investigators conducting cancer-relevant clinical research within Northwestern University, Northwestern Medicine, the Shirley Ryan Ability Lab (SRAL, formerly the Rehabilitation Institute of Chicago), the Jesse Brown VA Medical Center (JBVAMC), Ann & Robert H. Lurie Children’s Hospital of Chicago (LCH), and at sites participating in Lurie Cancer Center investigator-initiated trials (LCC IITs).

For purposes of this plan, a LCC IIT is a trial authored by a Lurie Cancer Center member or by any NU faculty member conducting cancer-relevant research. LCC IITs covered by this plan include studies supported through various funding mechanisms, including competitive NCI/NIH grants, other agency/sponsor grants or gifts, and grant-in-aid support from pharmaceutical sponsors. These trials are required to comply with the minimum requirements as described in this DSMP, or to develop an alternate plan that must be reviewed and approved by the Lurie Cancer Center’s Scientific Review Committee (SRC). Multi-center trials originating at an outside institution are required to submit a DSMP to the SRC for approval. If the originating site does not have a plan, they will be required to comply with the plan outlined in this document for the Lurie Cancer Center to be a participating site. As required by the NCI, other grants and contracts from NCI/NIH (e.g., National Clinical Trial Network studies) and studies developed and funded by industry are excluded from this plan.

## 2.3 Conflict of Interest

Conflict of Interest (COI) can include professional interest, proprietary interest, and miscellaneous interest as described in the NIH Grants Policy Statement and 45 CFR Part 94. NU has the following COI policies: “Policy on Conflict of Interest and Conflict of Commitment”, “Conflict of Interest in Research”, and “Institutional Conflict of Interest in Research”. These documents outline rules and reporting requirements governing all types of conflicts, including financial conflicts and disclosures, and also outlines policy specifically related to clinical research. Importantly, the NU policy requires that an investigator disclose if the value of any remuneration received from the entity in the twelve months preceding the disclosure and, in the case of publicly traded entities, the value of any equity interest in the entity as of the date of disclosure, when aggregated for the Investigator and members of his or her immediate family, exceeds \$5,000. NU employs an online, electronic system for reporting COI, and faculty and staff must report all significant financial interests (SFI) prior to engaging in research and at least annually thereafter; any new SFIs must also be reported within 30 days. These are reviewed by NU COI office and may be referred to the faculty member’s respective school and/or the COI Oversight Committee if additional review is required. If any COIs exist, the Dean’s office of the respective school and NU COI office will work with NU personnel to develop a plan to manage, reduce or eliminate the COI.

In addition to this University-wide policy, the NU Feinberg School of Medicine (FSM) has adopted a complementary policy titled “Disclosure and Professional Integrity Policy” developed with the integrity of medical research in mind. This policy also requires faculty to report financial COI, but there is no de minimis threshold for disclosure. Instead, all outside professional activities related to the health care industry are to be reported, no matter the payment amounts, and these are posted on the FSM website. Both the NU and FSM policies may be found online at [NU COI Policies](#).

Lurie Children’s has a “Financial Conflicts of Interest in Research and Sponsored Programs” policy that is applicable throughout the Lurie Children’s organization and requires disclosure of significant financial interest annually, using an online reporting system. Per their policy, significant financial interest in a publicly or non-publicly traded entity exists if the value of any remuneration received from the entity in

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the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. This policy is located online at [Lurie Children's COI Policy](#).

The Lurie Cancer Center's research oversight committees abide by Lurie Children's, NU and FSM COI policies. Any faculty member invited to serve on or to review items for any of the committees described in this DSMP must disclose any potential COI relevant to committee membership, whether real or perceived, to the appropriate Lurie Cancer Center officials (i.e., the cancer center Director and/or applicable committee leader). Potential conflicts that develop during a member's tenure on a committee must also be disclosed. Decisions concerning whether individuals with potential conflicts of interest, or the appearance of conflicts of interest, may participate on a committee or in a particular meeting will be made by the committee chair and/or co-chair.

While the Lurie Children's and NU policies outline general rules related to COI, the Lurie Cancer Center has established the following specific committee rules that govern the activity of members who have a conflict:

- A committee member may not vote on a protocol on which he or she serves as a Principal Investigator (PI) or sub-investigator. When a faculty member is present at an SRC meeting and a protocol on which he or she will be a PI or sub-I is being discussed in consideration for initial approval, he or she is required to leave the meeting during the discussion and committee vote on the project. The investigator is allowed to be present during discussion related to protocol revisions or data and safety monitoring issues; however, he or she may not vote on these items. He or she may also not serve as an auditor for his or her own trial.
- Any committee member who is not an investigator on a trial, but who has another identified conflict may or may not be allowed to vote on actions related to the protocol. This will be determined by the committee chair and/or co-chair. Those individuals found by the chair and/or co-chair to have a significant conflict related to a trial will not be allowed to vote on items related to that trial, as described above.

## 2.4 Confidentiality

All discussions that occur within any of the Lurie Cancer Center research oversight committees are confidential and are not disclosed except as outlined in this plan. Committee decisions are conveyed to the respective PI and other committees, as appropriate, on behalf of the entire committee via the meeting administrator, but no specifics are given related to the persons involved or details of the discussion that occurred. Any paper materials containing confidential information distributed during committee meetings are collected and destroyed after each meeting.

Further, the committees are especially aware of issues related to confidentiality of data. The committees abide by, and enforce, the design of each study; confidentiality of the data are maintained when data are presented (e.g., treatment assignment is not disclosed). Blinded studies remain so until they are to be un-blinded as per study design, or in response to a safety issue that requires knowledge of treatment received by a study participant.

## 3.0 INSTITUTIONAL CLINICAL TRIAL RISK ASSESSMENT AND MONITORING REQUIREMENTS

The Lurie Cancer Center expects that all LCC IITs will follow the data safety monitoring procedures and requirements outlined in this plan. This plan also applies to other (non-LCC IIT) clinical trials that do not

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have an acceptable external or alternate plan. This plan applies only to clinical trials, as defined in [Section 2.2](#) of this document.

### 3.1 Definitions of Levels of Risk and Associated Monitoring Requirements

The Lurie Cancer Center complies with federal regulations and guidelines, as well as the Lurie Children’s and NU IRB Office policies and procedures related to the assignment of trial risk. The “Northwestern Human Subject Protection Policy Manual” is found online at [NU IRB Policies](#). The Lurie Children’s “IRB Policy and Procedures Manual” is found at [Lurie Children’s IRB Policies](#).

The SRC defines three levels of risk for clinical trials, ranging from minimal to high risk. The level of risk is assigned irrespective of the type of intervention under consideration (e.g., therapeutic, prevention, supportive care, etc.), and all clinical trials that fall under the purview of this plan are assigned a level of risk. In the event that a study may be reasonably assigned to two categories, the highest risk category will be selected. Significant changes to the research during the conduct of the study may impact the risk level designation. The level of monitoring required will correspond with the level of risk assigned.

A variety of factors are taken into consideration in making this determination, such as the size, expected duration and complexity of a trial, the trial phase, safety measures included in the study design, study population, and the toxicity profile associated with the agent under investigation. The levels of risk are:

Level of Risk	Definition
<b>Minimal Risk</b>	<p>The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and where confidentiality is adequately protected. An example of this type of trial is a computer internet-based strategy aimed at increasing awareness of cancer issues, a dietary intervention, or exercise study aimed at symptom management.</p> <p>Monitoring by the Data and Safety Monitoring Committee (DSMC) is not required.</p>
<b>Moderate Risk</b>	<p>There is a probability of a moderate-severity event occurring but there is adequate safety monitoring in the trial to identify events promptly and to minimize their effects.</p> <p>An example of this type of trial is a topical agent used to control a drug rash.</p>
<b>High Risk</b>	<p>There is a high probability of the occurrence of a serious adverse event and/or study monitoring and reporting requirements of the trial are such that events or event trends may not be immediately recognized.</p> <p>AND/OR</p> <p>The NU or LCC investigator holds the IND/IDE.</p> <p>An example of this type of trial is a chemotherapy trial aimed at treating cancer.</p>

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### 3.2 Data and Safety Monitoring Boards

In instances in which there is a Conflict of Interest (COI) (e.g., clinical trials for drugs or devices that were developed from lab work done within the Lurie Cancer Center) the SRC and/or IRB may determine that a trial requires an independent Data and Safety Monitoring Board (DSMB). Composition of this board must be proposed by the study PI and approved by the SRC.

Phase III medical intervention trials have the further requirement of establishing an independent Data and Safety Monitoring Board (DSMB). Composition of this board must be proposed by the study PI and approved by the SRC.

Clinical trials that do not involve a drug or device intervention may require the establishment of an independent DSMB if required by the funding sponsor. These studies may present moderate risk, but additional safeguards are deemed necessary to ensure the trial is progressing acceptably. For example, the study may be comprised of several phases, each requiring data analysis prior to movement into the next phase. In a case such as this, an independent board is required to ensure an unbiased review of the data.

Clinical trials that are deemed minimal risk may require the establishment of an independent DSMB. These DSMBs are not required to report under this DSMP.

[Appendix D](#) outlines DSMB requirements for medical and non-medical intervention studies.

## 4.0 RESEARCH OVERSIGHT SYSTEM ORGANIZATION AND ADMINISTRATION

The Lurie Cancer Center has developed a comprehensive system of research oversight, comprised of distinct committees that work collaboratively to provide robust oversight of all aspects of clinical research conducted at the Lurie Cancer Center. The Scientific Review Committee (SRC) and the Disease Teams (DTs) comprise the Center's Protocol Review and Monitoring System (PRMS). The Data Monitoring Committee (DSMC) and the Clinical Trial Audit Committee (CTAC) are responsible for data safety monitoring and protocol compliance. The committees are independent and report directly to the Lurie Cancer Center Deputy Director. The Deputy Director, in turn, reports to the Director of the Cancer Center. Each committee or team includes a leader and co-leader as outlined below. A diagram of this system can be found in [Appendix A](#). Committee responsibilities related to data safety monitoring are described below.

### 4.1 Disease Teams

The primary objective of each DT is to guide in the selection and prioritization of high-quality cancer research studies. Each DT includes a team leader and co-leader, responsible for proper functioning of the team. A listing of DTs and their associated leaders may be found online at [Disease Team listing](#).

The DTs meet at least monthly to review all studies under the purview of their team. DTs must first endorse each newly proposed study before the protocol may be submitted to the SRC. In addition, DTs serve as the first level of review for Lurie Cancer Center investigator-initiated trials (LCC IITs); this is usually done at the concept or letter of intent (LOI) stage prior to full protocol development. The SRC, DSMC and CTAC communicate with the DT leaders as needed and will inform them of any issues or concerns that impact the DT's research portfolio. DSMC will send semi-annual reports for monitored studies as needed when issues arise, and CTAC will provide copies of all audit reports as applicable to the DTs.

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## 4.2 Scientific Review Committee (SRC)

The SRC is charged with the responsibility of evaluating new and enrolling clinical research protocols for scientific merit, institutional priority and ongoing progress, including review of accrual for all clinical trials. The SRC is an independent committee within the Lurie Cancer Center's PRMS, chaired by Al B. Benson III, M.D. and co-chaired by both Masha Kocherginsky, Ph.D. and Priya Kumthekar, MD. A full member listing is included online at [SRC membership](#).

The SRC is primarily focused on the scientific design and importance of new studies, as well as ensuring appropriate data and safety monitoring plans; SRC will not approve protocols that do not include an adequate DSMP. SRC review of LCC IITs includes assignment of risk level, which corresponds to the requirements for monitoring that are described in the final protocol. This decision is communicated to the DSMC. During ongoing progress review, SRC will notify the DSMC regarding any decisions that impact protocol status (e.g., suspension or closure) for those studies under DSMC purview.

The DSMC is responsible for informing the SRC of any findings that may impact the scientific integrity of a trial. In the event that the committee is notified of misconduct or other issues impacting study integrity the SRC will help ensure that all appropriate authorities are notified as needed (e.g., the IRB, FDA, NCI, funding sponsor, etc.). In the event that a suspension or closure occurs on an NCI funded trial, the SRC will ensure the PI reports to this the NCI Program Director.

## 4.3 Data and Safety Monitoring Committee (DSMC)

The DSMC plays an integral role in data and safety monitoring. This is a multidisciplinary committee that consists of a core group of individuals providing the necessary expertise in the principal disciplines of clinical hematology/oncology and radiation oncology with additional representation from biostatistics. Members are selected by area of expertise to form a diversified group of clinicians and other professionals able to provide rigorous monitoring of studies. Jochen Lorch, M.D. serves as chair of the committee and Sonali Chaudhury, M.D. is the co-chair. A full member listing is found online at [DSMC membership](#).

The Deputy Director of the Lurie Cancer Center provides oversight of the administration of the committee and also acts as a liaison between other clinical research oversight committees, investigators, and the Lurie Cancer Center Clinical Trials Office (CTO). The Lurie Cancer Center's Quality Assurance team provides administrative support for the committee, and each study monitor is responsible for reporting trials they monitor at the DSMC meetings. DSMC's review specifically focuses on participant safety and toxicity, outcomes/response, accrual updates, compliance issues, and overall data integrity (see [Section 5.1](#) for information related to monitoring activities).

The DSMC is an independent committee responsible for safety review and study progress monitoring for Lurie Cancer Center investigator-initiated clinical trials. Trials whose monitoring plan falls under the institution's DSMP will also be monitored accordingly. While the DSMC is a distinct independent committee, DSMC shares its findings with the other committees of the Research Oversight System, as needed. In particular, DSMC will notify SRC of any issues they believe to be potentially relevant to the scientific integrity of the trial. The DSMC will also communicate with Disease Teams, informing them of any concerns, and sends the team leaders semi-annual reports as necessary for relevant LCC IITs.

The DSMC meets monthly and provides the following:

- [Ongoing Study Monitoring](#): DSMC reviews the progress of all clinical trials monitored by the committee through review of semi-annual reports. The semi-annual reports include such

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information as accrual, reported adverse events, and compliance issues. These are completed collaboratively by the PI and assigned QAM. Studies not directly monitored by the NU QAM team will follow protocol-specific procedures. These reports will continue until trial is closed to further enrollment, all patients are off study intervention, and no new enrollment, safety, compliance information is expected. If the DSMC has a recommendation regarding accrual, safety and toxicity, compliance or data compliance, SRC and the associated DT will be notified of the recommendation.

- FDA Report review: DSMC is responsible for the review of all FDA annual reports prior to submission to the FDA for those studies where the Lurie Cancer Center PI holds the IND or IDE.
- Safety review: DSMC conducts ongoing safety reviews of all clinical trials monitored by the committee. Safety review includes a listing of all reportable adverse events, as specified in each protocol, that occur on the trial. The DSMC has the authority to suspend or close any study if serious safety concerns are identified.
- Serious Adverse Event (SAE) review: DSMC reviews all SAEs that occur on trials monitored by the committee. Initial reports are reviewed at the first DSMC meeting after receipt of the completed event report per protocol. Any change in event term, grade, or relationship to study agent will require re-review. All SAEs are also included in aggregate for review by DSMC as part of the semi-annual report.
- Dose Limiting Toxicity (DLT)/Dose Escalation review: DSMC, in conjunction with the study assigned statistician, reviews all potential DLTs for Phase I dose-escalation studies. Protocol suspensions and re-opening of accrual to the next cohort, based on DLT evaluation, fall under the purview of DSMC.
- Stopping Rule review: DSMC, in conjunction with the study assigned statistician, will assess safety data and critical efficacy endpoints at intervals defined by the protocol and recommend whether to continue, modify, or stop a trial.
- Protocol Deviation review: All protocol deviations will undergo an initial review by the QAM. Those determined to be potentially reportable to the IRB or represent continued noncompliance will also be reviewed by the DSMC at the next meeting. If the DSMC determines a deviation is reportable to the IRB, the QAM communicates this information to the study's assigned regulatory coordinator and study team, and they work together to submit this to the IRB. Studies not directly monitored by the NU QAM team will follow protocol-specific procedures. All protocol deviations, including those not initially reviewed by DSMC, are reviewed in aggregate by the DSMC as part of the semi-annual report. The DSMC further has the authority to suspend or close the trial in the event that major protocol compliance issues are found.
- Reportable New Information (RNIs): All RNIs requiring reporting to the Northwestern or Lurie Children's IRB will be reported to the DSMC at the next meeting. For more information on what constitutes an RNI, please see <https://irb.northwestern.edu/index.html>. The only caveat to this rule will be short form consents, which are approved through the RNI mechanism, but do not require DSMC review.
- Data Set review: Data requests to be used for abstract and/or manuscript development must be reviewed and approved by the DSMC prior to release to the study PI and/or biostatistician. Data will be released in accordance with the [Data Release policy](#).

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- **Audit Report review:** DSMC reviews audit reports submitted by CTAC. In particular, CTAC submits audit reports and corrective and preventative action plans (CAPAs) to the DSMC for any audit findings that relate to data integrity or patient safety. The DSMC has the authority to require further corrective action if the submitted plans are determined to be insufficient to address the findings. In the event that any issues are identified with a trial, the DSMC notifies the PI of the issue(s) and may request a response or a more formal Corrective and Preventative Action Plan (CAPA). The DSMC further has the authority to suspend or close the trial in the event that major concerns are found during an audit. The DSMC is responsible for reporting any findings that affect the scientific integrity of the trial to the SRC.

If the decision is made to suspend, re-open, or close a study, this change is made by the study assigned Quality Assurance Monitor (QAM) within the Lurie Cancer Center’s clinical trials management system (NOTIS), and this generates an automatic notice of study status change to the PI and study team. Studies not directly monitored by the NU QAM team will follow protocol-specific procedures.

#### 4.4 Clinical Trial Audit Committee (CTAC)

The CTAC is responsible for overseeing the conduct of the Lurie Cancer Center’s auditing program. The committee consists of members providing expertise in clinical oncology and research compliance and forms a diversified group of professionals able to provide rigorous oversight of auditing activities. This committee is chaired by Jessica Altman, M.D. and co-chaired by Sunandana Chandra, MD. A full member listing is provided online at [CTAC membership](#).

The Lurie Cancer Center’s Quality Assurance team designee provides administrative support for the committee, and assembles an independent audit team for each audit, which may include faculty members, fellows, nursing staff, and CTO staff. To avoid COI, the faculty and staff cannot be chosen to audit a trial for which they are listed on the IRB’s authorized personnel list. CTAC’s review specifically focuses on audit scheduling and conduct and review of audit findings.

The CTAC is an independent committee responsible for overseeing the conduct and outcome of audits of Lurie Cancer Center investigator-initiated clinical trials. Trials whose monitoring plan falls under the institution’s DSMP will also be audited accordingly. While the CTAC is a distinct independent committee, CTAC shares its findings with the other committees of the Research Oversight System, as needed. In particular, CTAC will provide DSMC a copy of the audit report as indicated in [Section 4.3](#). Suspensions initiated by the CTAC will also be reported to the DSMC. The committee communicates findings to the DSMC and may:

- Recommend that the DSMC close a study to further accrual;
- Recommend membership termination for a site due to substandard performance; and
- Recommend changes to policy, protocols, or procedures based on cumulative audit findings.

The CTAC meets bi-monthly or as needed based on the current audit schedule and provides the following:

- **Audit scheduling and conduct:** The CTAC administrator schedules audits, assigns auditors, and ensures audits are conducted as required, under the supervision of the CTAC. Audits are conducted following the [NCI’s Clinical Trials Monitoring Branch Auditing Guidelines](#). CTAC leaders are available to advise on audit activities, answer questions as needed, and attend key audits, as needed.

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- Review of audit findings: CTAC reviews all audit findings and makes the final determination on the seriousness of issues identified during the audit. Individual findings are categorized as “lesser” or “major”, following NCI CTEP definitions. The committee will determine if the PI must submit a Corrective and Preventative Action Plan (CAPA), assesses the final audit outcome, and recommends measures for the subsequent audits. CAPAs from prior audits will also be reviewed by the CTAC.
- Cause-specific review of audits with major violations: CTAC pays particular attention to major and recurrent audit findings and has the authority to suspend study accrual for continued non-compliance. If the decision is made to suspend a study, this change is made by the study assigned QAM within the Lurie Cancer Center’s clinical trials management system (NOTIS), and this generates an automatic notice of study status change to the PI and study team.
- Administrative activities: CTAC advises leadership on audit-related activities, outcomes, and policy issues. They also assist in the development of quality assurance tools, measures and SOPs.

Audits will focus on trials assessed as high-risk and will be audited according to the following plans:

- Comprehensive (Routine) Audits – At least one case, or 10% of participant case accrued since the last audit, will be audited. A representative sampling should be chosen for audit. These are comprehensive audits that include, as applicable to the trial, a review of:
  - Regulatory Documentation, including IRB, Informed Consent Content, Delegation of Authority
  - Accountability of Investigational Agents and Pharmacy Operations
  - Patient Case Records, including informed consent, eligibility, treatment, evaluation of disease outcome/tumor response, reporting of adverse events, and general data quality
- First Participant (Routine) Audits – The first participant to enroll on a trial at the lead institution and the first participant enrolled on a trial at each collaborating site, if applicable, will be audited. The case audit occurs after the first participant has completed the first response assessment or goes off active intervention, whichever comes first. These audits may count towards the comprehensive audit as applicable. These audits include patient case review only.
- For-Cause Audits – Trials at risk of non-compliance, or suspected or reported non-compliance may be undergo additional auditing measures. These audits may occur at any time and advanced notice is not required. These audits may consist of a limited or comprehensive review.

#### 4.5 Lurie Cancer Center Research Oversight Committees and the IRB

NU and Lurie Children’s each have independent IRBs but also have a signed Authorization Agreement that allows collaboration for the review of studies impacting both institutions. The SRAL is contracted to use the NU IRB. NU IRB provides six IRB panels, including five that meet monthly and one that meets weekly (for continuing reviews and other time-sensitive submissions). The Lurie Children’s IRB Office provides support for two panels that meet bi-monthly. NU faculty may also use a central IRB for certain types of studies. The Jesse Brown VA Medical Center has an independent IRB that meets twice a month. All new cancer-relevant protocols and revisions must receive the appropriate SRC, IRB, and other required institutional approvals prior to activation or implementation.

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The SRC and IRB perform separate but complementary activities, which do not overlap or duplicate effort. The Lurie Cancer Center oversight committees are responsible for scientific review, monitoring, and evaluation of trials for ongoing progress, data and safety monitoring, and auditing. The IRB is responsible for the overall ethical and safety considerations of clinical research with respect to protecting the rights and welfare of human subjects involved in research. Additionally, the IRB ensures that all consent forms adequately express the risks, benefits, alternatives, and financial costs of clinical research protocols. The IRB further ensures HIPAA regulations are followed. [Appendix B](#) provides a comprehensive diagram of the relationships among these committees and with the Institutional Review Board (IRB).

## **5.0 QUALITY ASSURANCE MONITORING**

The Lurie Cancer Center has made it a priority to continuously strengthen our internal quality assurance program. Quality assurance and quality control is an independent office within Lurie Cancer Center, reporting administratively to the Administrative Director, Clinical Trials, of the Cancer Center. To ensure adequate quality controls at all levels of clinical research has required the interaction of a number of Lurie Cancer Center employees, oversight by the DSMC and CTAC, and the participation of the Biostatistics Core Facility. Currently there are two procedures in place for quality oversight: quality assurance review and internal audit, which is overseen by CTAC.

### **5.1 Quality Assurance Review**

Quality assurance review is the responsibility of six Quality Assurance Monitors (QAMs) who report directly to the office’s Quality Assurance Operations Manager (QAOM). The QAMs are responsible for the ongoing review of all clinical trial data for LCC IITs, concentrating on data accuracy and completeness, protocol adherence, and safety review. This includes the review of studies that are supported by competitive federal funding mechanisms that do not have an alternate data management plan.

The QAMs review data submitted for trials at scheduled monitoring visits, according to the monitoring plan associated with the study’s risk level, and they interact directly with each study PI as issues arise. They also work directly with treating physicians and study coordinators, both at the Lurie Cancer Center and at participating sites, if there are issues related to study participants and/or data submission. The QAMs regularly report all findings directly to the DSMC during monthly meetings and via email, when needed.

The QAMs are intimately involved in data capture and review from protocol implementation through trial completion. Trials opened prior to July 2009 use paper-based case report forms, created by the QAMs. All LCC IITs assessed as moderate or high-risk and opened to accrual after July 2009 use electronic case report forms (eCRFs), built into NOTIS, the Lurie Cancer Center’s clinical trial management system. The study assigned QAM builds eCRFs for each new trial. To ensure appropriate forms are used for each study, the QAOM and QAMs thoroughly review each new project, and revisions to ongoing projects, to determine eCRF needs. This review includes discussion with the study PI, biostatistician, study coordinator, data manager and/or other study team members to review study objectives, eligibility requirements and registration process, trial design, treatment plan, adverse event reporting requirements, measurement of outcomes and study parameters. The developed forms are the only CRFs used to collect data and are used by the QAMs to monitor the study.

The intensity of monitoring activities varies by the study assigned risk. Based on the outcome of any monitoring activities, additional monitoring parameters may be recommended. An overview of the monitoring requirements for each level of risk is indicated in the table below. Additional information on

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frequency and volume of monitoring activities are explored in the RHLCCC Quality Assurance Monitoring Guidelines.

Level of Risk	Monitoring Overview
<b>Moderate Risk</b>	<ul style="list-style-type: none"> <li>• requires use of NOTIS for registration and reporting of adverse events               <ul style="list-style-type: none"> <li>○ Other types of data are not required to use NOTIS eCRFs</li> </ul> </li> <li>• requires prospective registration of participants</li> <li>• requires timely submission of adverse event eCRFs, according to protocol</li> <li>• requires submission of any adverse events meeting expedited reporting criteria to be promptly reported to the QAM, according to protocol</li> <li>• Semi-Annual Report and SAE review will be reviewed by DSMC as indicated in <a href="#">Section 4.3</a></li> </ul>
<b>High Risk</b>	<ul style="list-style-type: none"> <li>• requires use of NOTIS for registration and reporting of all study-related data</li> <li>• requires prospective registration of participants</li> <li>• requires timely submission of all eCRFs, including adverse events, and will be monitored in a risk-based approach</li> <li>• requires submission of any adverse events meeting expedited reporting criteria to be promptly reported to the QAM, according to protocol</li> <li>• Semi-Annual Report, FDA Report, safety, SAE, DLT/Dose escalation, stopping rule, protocol deviation, RNI, data set, and audit report review will be reviewed by DSMC as indicated in <a href="#">Section 4.3</a></li> </ul>

## 5.2 Other Quality Assurance Activities for High-Risk Studies

The QAMs work closely with faculty and staff throughout the life cycle of each protocol, from initial protocol development through final data analysis and study termination. New LCC IITs require a Study Implementation Meeting (SIM), which is a meeting that brings together members of the study and extended care teams, to ensure the study is feasible and that the protocol document is clear and easy to follow. The QAMs are important participants in the SIM, providing valuable input on the protocol document, including such things as ensuring registration procedures and other QA activities are adequately described. The QA team additionally reviews the protocol again at SRC review, to ensure QA activities are adequately described, and ensure the trial is assigned an accurate risk level. It is during this early stage that the QAMs also work with the PI and study team to develop eCRFs for the study.

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The Quality Assurance Team is also responsible for preparing all data for submission for publication and presenting to the DSMC for review and approval as described in DSMC Data Release Policies and Processes that was developed with our Quantitative Data Sciences Core.

### 5.3 Adverse Event Reporting Requirements

Adverse event reporting requirements and timing of reporting are dependent on the phase of the trial, as well as the grade and attribution of the event and is completed as outlined in the guidelines published in the NCI Investigator Handbook

([http://ctep.cancer.gov/investigatorResources/investigators\\_handbook.htm](http://ctep.cancer.gov/investigatorResources/investigators_handbook.htm)). It is the responsibility of the study PI, the treating physician, and clinical team to identify events as they occur. Federal guidelines require timely reporting of all unanticipated adverse events as outlined by the study sponsor.

All Serious Adverse Events (SAEs) must be reported as required by institutional policy and federal guidelines. In addition, adverse events which do not meet the definition of a SAE may also require expedited reporting dependent upon the grade of adverse event, attribution, and whether the event is expected or unexpected. Expedited reporting may not be required for protocols when the adverse event is expected. Any exceptions will be outlined in the text of the protocol. In the event that a participant experiences an event requiring expedited reporting, the report must be submitted to the QA team, IRB of record, and federal agency (as applicable) using appropriate reporting forms.

21 CFR 312.32, defines a SAE as an adverse drug experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse drug experience;
- Inpatient hospitalization or prolongation of existing hospitalization (for > 24 hours);
- A persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly or birth defect;
- Important Medical Events that may not result in death, be life threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

Whenever a serious adverse event occurs on an LCC IIT, either at the Lurie Cancer Center or a participating site, the event is submitted to the QAM and is reviewed by the DSMC. The DSMC will review the event and the PI's assessment. For events occurring at a participating site, the lead site PI will also review the event and local PI's assessment. The DSMC may determine the event requires expedited reporting, and in this case, the QAM will follow-up with the PI to help ensure the event is reported to the IRB of record. If an event is determined to require expedited reporting to the IRB, it will also be sent to participating sites as a Suspected Unexpected Serious Adverse Reaction (SUSAR) report requiring IRB submission and consent and/or protocol modification will be sent to the sites as appropriate. See [Appendix C](#) for flow diagrams outlining procedures for handling of both internal and external adverse events.

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The CTO regulatory team is responsible for processing external SUSARs and ensuring these are reviewed by PIs who hold an IND/IDE for that drug or device. The QAMs then present SUSARs that qualify as RNIs to the DSMC. Any event determined by the DSMC to be a UPIRSO is routed to participating sites for local IRB submission and consent and/or protocol modification will be sent to the sites as appropriate.

For all NCI funded or sponsored clinical trials, investigators are required to submit events through the CTEP Adverse Event Reports System (CTEP AERS) as described in the “NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs” found at [https://ctep.cancer.gov/protocoldevelopment/adverse\\_effects.htm](https://ctep.cancer.gov/protocoldevelopment/adverse_effects.htm).

If NCI does not hold the IND, the FDA regulations apply as outlined in 21 CFR Part 312.32

(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.32>).

If the trial uses commercially available agents/devices SAEs are reported using a format as indicated in the trial or are reported through MedWatch (<http://www.fda.gov/>).

If the trial involves recombinant or synthetic nucleic acid molecules, the reporting requirements described above must be followed. In addition, the “NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)” apply. This guideline may be found at <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>.

If the trial is a post-marketing vaccine trial, the reporting requirements described above must be followed. In addition, adverse events may be submitted through the Vaccine Adverse Events Reporting System (VAERS). Further information regarding vaccine adverse event reporting is found at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/default.htm>.

The NU IRB requirements for events that may be considered Reportable New Information (RNI) can be found online at <https://irb.northwestern.edu/index.html>. Those events determined to be Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) be submitted within 5 working days of the event. A UPIRSO is an event that is unexpected, related or possibly related, and suggests greater risk. More information on this policy can be found at <https://irb.northwestern.edu/index.html>. The Lurie Children’s IRB and the Jesse Brown VA Medical center have similar reporting requirements. The Lurie Children’s policy is described in the “IRB Policy and Procedures Manual” located online at <https://www.luriechildrens.org/en/research/management/research-integrity-compliance/irb/>, and the VA Policy is outlined online at [http://www.va.gov/ORO/Docs/Guidance/1058\\_01\\_Decision\\_Chart\\_Rsch\\_Death\\_SAE\\_Problem\\_09\\_14\\_2015.pdf](http://www.va.gov/ORO/Docs/Guidance/1058_01_Decision_Chart_Rsch_Death_SAE_Problem_09_14_2015.pdf).

If the trial involves behavioral or nutritional interventions that do not use an investigational agent, there are no standard grading scales for adverse events. Therefore, defining suitable grades for adverse events is the responsibility of individual investigators for each protocol. Adverse events of a psychological nature can occur with behavioral trials and should be specified for the particular intervention in question.

## **6.0 MULTI-CENTER TRIAL ADMINISTRATION**

The Lurie Cancer Center has established Standard Operating Procedures (SOPs) that are used for the management of multi-center LCC IITs. These procedures include activities related to site qualification, pre-activation, protocol training, trial initiation, and clinical and regulatory communications. Activities

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related to the Lurie Cancer Center oversight committees are addressed in all these areas and are described below.

## 6.1 Site Qualification and Trial Initiation

The Lurie Cancer Center has a dedicated Project Manager who provides oversight for our affiliate network and works directly with the network and other sites participating on LCC IITs. Communications related to study start up and ongoing regulatory compliance are directed by this Program Manager.

When the Lurie Cancer Center is informed of a potential new site for an LCC IIT, the multi-site project manager sends the site a packet of information, including the Participating Site Data Compliance Policy. The packet must be completed by each new participating site, and all completed forms are returned to and reviewed by the Multi-Site Compliance Program Manager to determine if a site is a good candidate for the trial. The Project Manager reviews the PI's data delinquency status on other studies, as applicable. If the PI is in good standing and a confidentiality disclosure agreement is in place, the site may be approved and allowed to submit the Lurie Cancer Center IRB approved version of the protocol to their local IRB. Each new site PI must sign and return the Data Compliance Policy before any activity related to a study may begin.

While a participating site is awaiting local IRB approval, other site pre-activation activities may begin. During this time, the multi-site project manager collects required regulatory documents (e.g., signed 1572, financial disclosure forms, medical licenses, contracts, etc.). In addition, a site initiation visit (SIV) is required for all studies (which may be performed by teleconference), and the site will receive training on eCRFs. The site will be activated once all required pre-activation requirements are complete and their documentation of IRB approval has been received.

## 6.2 Active Trial Communications

Unless an alternate monitoring plan has been approved by the SRC, all sites participating in LCC IITs are expected to comply with this DSMP. As such, all sites will use the Lurie Cancer Center created eCRFs designed for the study. All data are submitted to the assigned QAM, as described in each study. The data is monitored by the QAM and reviewed by DSMC as described in this plan.

Participating site clinical and regulatory data are included in the auditing program. When a participating site case is selected for audit, the site is informed of this and is expected to submit all source documents for inclusion in the audit. In addition, regulatory documents and pharmacy logs must also be submitted for inspection. Sites are expected to comply with all requests of the CTAC.

## 6.3 Consortium Trials

In the event that in LCC IIT is activated through a consortium, the consortium may elect to use the Lurie Cancer Center's Data and Safety Monitoring Plan as the monitoring plan of record. In such cases, quality assurance activities usually performed by the Lurie Cancer Center Quality Assurance department may be delegated to a Contract Research Organization. Any organization that manages quality assurance activities on such trials must explicitly agree to adhere to the Lurie Cancer Center Data and Safety Monitoring Plan and must report regularly to the Data and Safety Monitoring Committee.

# 7.0 INVESTIGATOR RESPONSIBILITIES

While the Lurie Cancer Center research oversight committees hold a great deal of responsibility for trial monitoring, the PI of each study is ultimately responsible for every aspect of the design, conduct, and final analysis of the protocol. All PIs are required to complete all institutional training requirements, abide

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by federal policies and guidelines, and abide by those commitments outlined in FDA Form 1572/Investigator Agreement. In addition, the study PI must ensure that:

- All protocols include a data and safety monitoring plan (either this plan or a plan developed by the PI and approved by the SRC).
- All studies have a structured adverse event determination, monitoring, and reporting system, including standardized forms and procedures for referring and/or treating participants experiencing adverse events.
- The proposed schedule for reporting adverse events to the QAMs, IRB, and appropriate federal agencies is described in the protocol.
- In specific cases where an outside agency is the sponsor of the test agent, (i.e., holder of the IND), PIs must submit individual adverse event reports to the funding agency/sponsor in accordance with sponsor and FDA regulations.
- With the assistance of CTO staff, participating sites enrolling in multi-center trials are kept informed of unanticipated SAEs and/or any problems identified by the DSMC or IRB.
- Semi-annual reports are reviewed and per DSMC guidelines.
- The appropriate committees of the research oversight system and applicable personnel are informed of actions, if any, taken by the IRB as a result of Continuing Review or any other IRB submission (e.g., Reportable New Information).
- With the assistance of the CTO regulatory staff (or other personnel if not managed by the CTO), DSMC, SRC and CTAC reports are submitted to the IRB of record per their requirements.
- All decisions made by the research oversight committees are adhered to (e.g., protocol suspensions or closures).
- The informed consent document is complete and accurately reflects the risks and other essential information as part of the initial submission to the SRC. In the event that a waiver of consent will be requested, a justification must be submitted to the IRB.
- All blinded studies describe a randomization scheme and specific criteria and procedures for unblinding.
- All data used for abstracts and publications of LCC IITs have been reviewed and approved by the DSMC prior to use.
- In the case where the Lurie Cancer Center PI is an IND/IDE holder, all FDA reporting requirement to maintain the IND/IDE are followed. This is done with the assistance of the QAMs.
- In accordance with NIH policy released September 22, 2000 entitled “Notice To NIH Grantees/Contractors Regarding Letters Or Notices From The Food And Drug Administration (FDA),” the Lurie Cancer Center requires the PI of any IND or IDE trial receiving federal funds to inform the awarding Institute of significant communications from FDA.

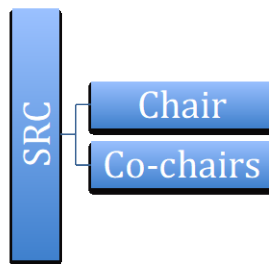
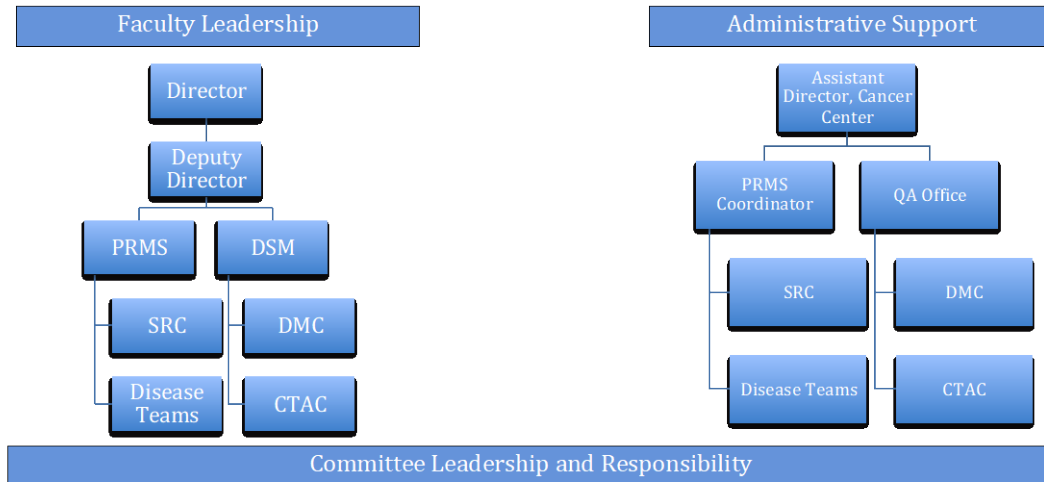
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- As per NCI requirements, the NCI Program Director responsible for funding a trial must be informed of any communication affecting the status of NCI-sponsored trials (e.g., trial suspension or closure).
- In accordance with federal policy, the PI is responsible for clinicaltrials.gov trial registration and reporting.

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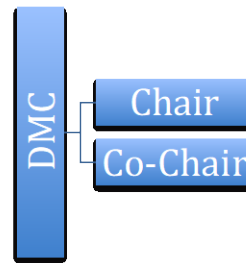
# Appendix A: Lurie Cancer Center Research Oversight System

## Lurie Cancer Center Research Oversight System



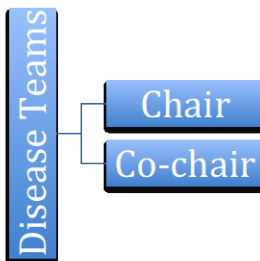
**Responsibility:**

- Initial independent scientific review, interventional trials
- Approval of prioritization, interventional trials
- Ongoing monitoring, interventional trials
  - Scientific changes
  - Accrual
- Administrative review, non-interventional research



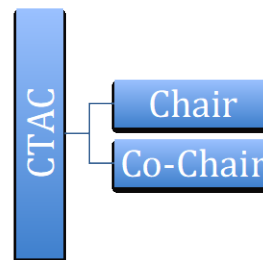
**Responsibility:**

- Administer DSMP
- Release of approved data to PI for abstracts, publication



**Responsibility:**

- Initial scientific review/interventional trials
- Prioritization, interventional trials
- Dynamic/ongoing accrual review, interventional trials

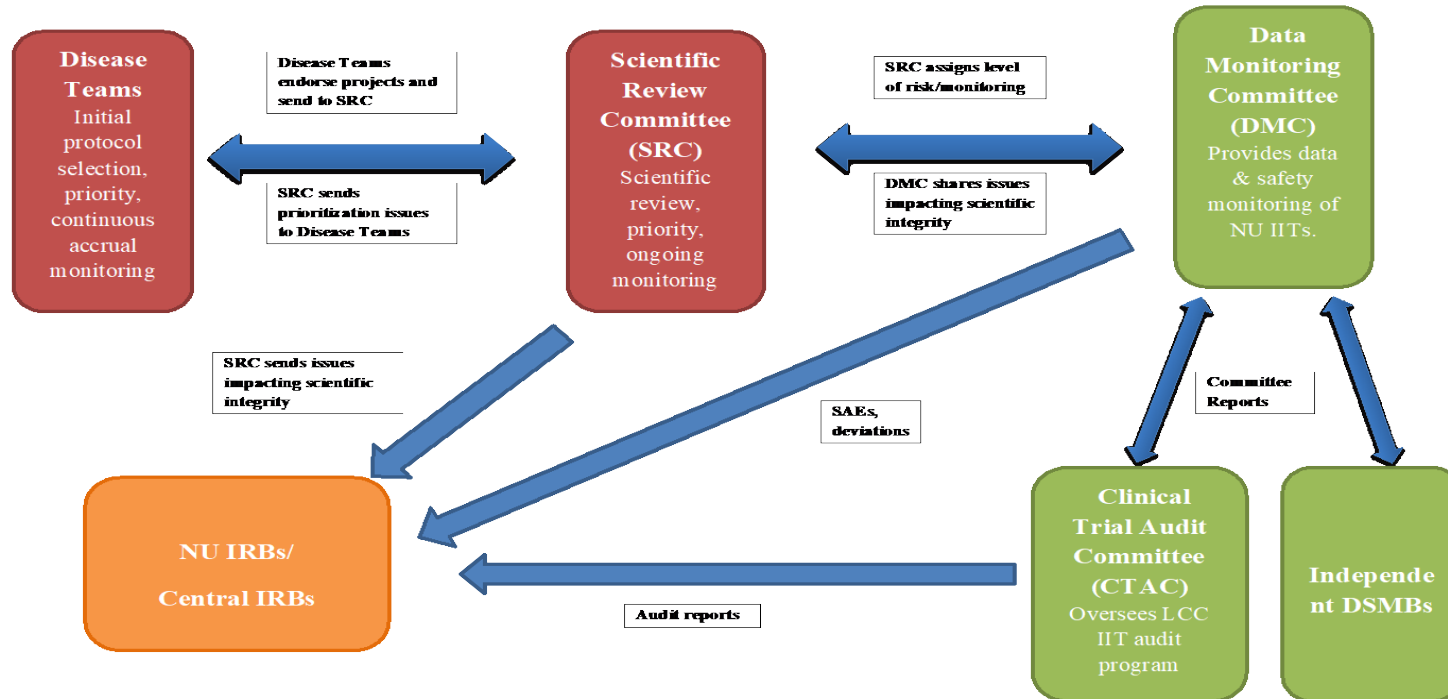


**Responsibility:**

- Oversight of audit process
- Review of audit reports
- Review and approve of CAPAs

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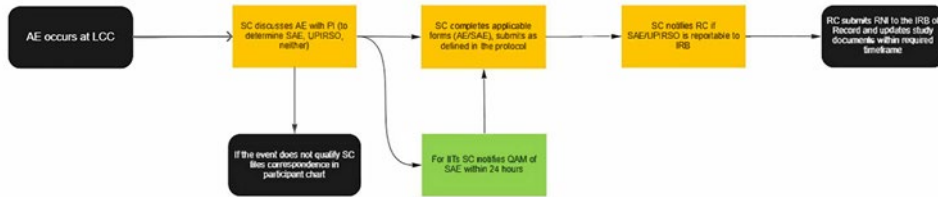
## Appendix B: Lurie Cancer Center Research Oversight System Activity Flow Diagram



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# Appendix C: Adverse Event Management

## LCC - All Study Types



## LCC - Participating Sites





## **Appendix D: Guidelines for the Establishment of Data and Safety Monitoring Boards (DSMBs) Medical Intervention Clinical Trials**

DSMB composition should meet the minimum requirements set forth by the NCI.

<https://www.hhs.gov/guidance/document/nci-policy-data-and-safety-monitoring-clinical-trials>

<https://grants.nih.gov/policy/humansubjects/policies-and-regulations/data-safety.htm>

External DSMBs will be reviewed by SRC and final listing of membership and complete DSMB charter should be sent to [SRC.CCSG@northwestern.edu](mailto:SRC.CCSG@northwestern.edu)

1. The DSMB members, including the chair, must agree to serve on the board. Their approval should be documented and maintained in the trial files.
2. The PI will work to create a DSMB Charter, outlining the requirements and expectations of the DSMB.
  - a. The charter should include the name, credentials, and contact information for each member.
  - b. It is also recommended that the administrative assistant contact information for each member is provided as well.
  - c. The charter should include information on the release of data, confidentiality and conflict of interest
3. Prior to activation, the DSMB should understand their obligations on the board, as defined by the protocol and/or DSMB charter.

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## Non-Medical Intervention Clinical Trials

DSMB creation for non-medical intervention clinical trials will be at the discretion of the PI and will not fall under the DSMP. If a DSMB is formed, it should follow the guidance for interventional trials.

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