University of New Mexico
Cancer Center and New Mexico Cancer Care Alliance
Data and Safety Monitoring Plan
2010

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DSMP Version 11/10: The DSMP has been revised to include the following changes in the document;

- To include a specific description of the New Mexico Cancer Care Alliance and its relationship to the University of New Mexico Cancer Center
- To clarify the role and authority of the Protocol Review & Monitoring Committee (formerly the Medical Scientific Review Committee MSRC) and the Data Safety Monitoring Committee (formerly the Protocol Monitoring Committee)
- To create a monitoring process for investigator initiated trials which results in real time oversight by the DSMC and to increase the monitoring of Very High Risk protocols to monthly frequency
- To add biostatistics expertise to the review functions of the DSMC.
- To officially define that the position of Medical Director of the New Mexico Cancer Care Alliance is separate from the Medical Director of the Clinical Protocol, Data Management and Informatics

These items have been approved by the Clinical Research Committee, the quality oversight entity for clinical research at the University of New Mexico Cancer Center.

This DSMP was approved by the NCI June 23, 2011.

This DSMP was revised under advisement of the NCI to remove the PRMS, June 30, 2011.

Summary

The University of New Mexico Cancer Center (UNM CC) places a high priority on ensuring the safety of patients participating in clinical trials. All clinical trials require monitoring commensurate with the degree of risk involved in participation of studies. Standard Operating Procedures (SOP's) detail functions and processes found in this plan. SOP's are available at http://hsc.unm.edu/UNM CC/intranet/ctoforms.asp.

Data and safety monitoring activities for each study continue until all patients have completed their treatment and all patients are beyond the time point at which study-related adverse events would likely be encountered. The UNM CC has implemented a process for routine real time data monitoring and safety review of Investigator Initiated trials which takes into account the Essential Elements of the National Cancer Institute (NCI) guidelines, the FDA monitoring regulations, Good Clinical Practice Guidelines and other DSM plans and programs approved by the NCI. The end result is:

1. ***Monitoring the progress of trials and the safety of participants.***
2. ***Plans for assuring compliance with requirements regarding the reporting of adverse events (AEs).***
3. ***Plans for assuring that any action resulting in a temporary or permanent suspension of an NCI-funded clinical trial is reported to the NCI grant program director responsible for the grant supporting that trial.***
4. ***Plans for assuring data accuracy and protocol compliance, including minimization of risks.***

This document is intended to provide investigators with a Data Safety Monitoring Plan (DSMP) for all phases of cancer clinical trials, in accordance with National Institutes of Health (NIH) and NCI requirements. The NIH/NCI suggests that institutions sponsoring a significant number of clinical trials formulate a DSMP that can be broadly applied to the individual trials in their portfolio. Trials which originate from sponsors outside of UNM CC and the NMCCA have their own DSMPs, to which this DSMP defaults. This DSMP specifies the process for monitoring and auditing those studies which are investigator-initiated, for which a DSMP does not already exist. However, the studies which utilize another DSMP are still part of the internal auditing and Quality Assurance program discussed in this DSMP. The UNM CC DSMP is created and maintained by the Chair of the Data Safety Monitoring Committee (DSMC). The UNM CC DSMP will be reviewed and revised if needed on an annual basis at minimum, by the DSMC, and revisions forwarded to the Clinical Research Committee (CRC). The CRC approves these, and then forwards any revisions to the UNM CC Director and CEO, who has the final review and right of approval.

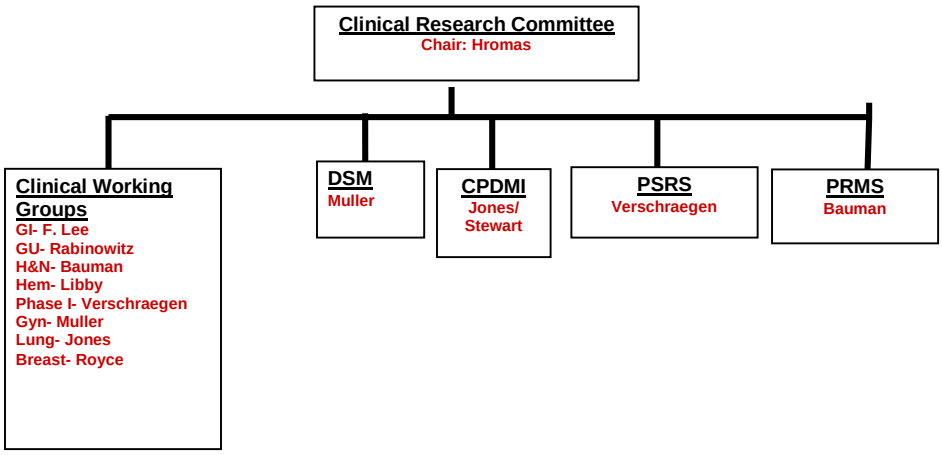
In addition to complying with NIH/NCI guidelines, the UNM CC DSMP complies with, the University of New Mexico Health Sciences Center Human Research Protections Office (HRPO) guidelines for safety and data monitoring (http://hsc.unm.edu/som/research/hrrc/PoliciesGuidelines.shtml). The DSMP is distinct from, and complements, the activities of the Protocol Monitoring & Review Committee (PRMC) and the Clinical Protocol Data Management & Informatics (CPDMI) functions of UNM CC. The UNM CC DSMP covers all clinical research activities of the UNM CC and its community partners through the New Mexico Cancer Care Alliance (NMCCA) and the Minority Based Community Clinical Oncology Program (MB-CCOP).

The New Mexico Cancer Care Alliance (NMCCA) is a New Mexico nonprofit 501(c)(3) charitable organization that was founded in 2002. It is a scientific and educational organization, and a growing network of 120 physicians who practice in major health care institutions throughout the state of New Mexico. The original purpose was to increase access to novel treatments and cancer-related clinical research through the community, often within the offices and clinics of participating physicians and organizations. NMCCA provides a central point of contact for all study-related regulatory efforts, contracting, trial monitoring, and data storage throughout its network. Member institutions and practices include the Lovelace Healthcare System, Memorial Medical Center, Las Cruces; New Mexico Veterans Affairs Medical Center—Albuquerque; Presbyterian Healthcare Services, Christus St. Vincent Regional Medical Center, Santa Fe; and the University of New Mexico Cancer Center, Albuquerque.

More detail can be found at www.nmcca.org.

Thehe UNM CC is a member of the NMCCA, and the NMCCA offices are physically located within the Administrative Wing of the UNM CC. The Protocol Review & Monitoring Committee (PRMC) is comprised of members from all NMCCA practices., Though the DSMC is under the control of UNM CC, it includes oversight of UNM CC investigator initiated trials performed at NMCCA sites.

The Protocol Review and Monitoring System (PRMS) which is managed by the PRMC is an essential component of the conduct of cancer clinical research at the UNM Cancer Center. The PRMC has the authority to open protocols that meet the scientific merit and scientific progress of the UNM CC and to close protocols that do not demonstrate scientific progress. The PRMC works with the disease specific clinical working groups (CWG) to approve and prioritize these studies. The PRMC assigns the risk of approved protocols, which is one criterion for the frequency of ongoing monitoring by the DSMC. The DSMC is responsible for ongoing real time monitoring of investigator initiated trials at UNM CC and is responsible for monitoring patient safety and closing trials for safety reasons. The Clinical Research Committee (CRC) is the committee which provides strategic planning and quality oversight of overall performance of the Clinical Trials Office and integrates all clinical oncology research efforts at the UNM Cancer Center. The Clinical Research Committee does not review and alter decisions made in protocol review and monitoring process, but rather ensures that such review and monitoring is properly performed and is of high quality. The Director and CEO of the UNM CC holds overall responsibility for overseeing data and safety monitoring, and is assisted by the DSMC in this function as the data safety monitoring board for all UNM CC and the NMCCA investigator-initiated trials.



The DSMP is in keeping with recent recommendations from the NIH and the FDA, as detailed at the following web sites:

http://grants.nih.gov/grants/peer/hs_review_inst.pdf
http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://www.fda.gov/cber/gdlns/clindatmon.htm
http://www.ncrr.nih.gov/clinical/patientsafety20010622.html
http://www.nci.nih.gov/clinicaltrials/conducting/dsm-guidelines

Faculty and staff are required to review the DSMP and complete an attestation that they have done so. Documentation is maintained in the Clinical Trials Office of Quality Assurance. The UNM CC Members are not permitted to submit an investigator initiated trial application unless the training has been completed. The current DSMP for clinical trials is maintained and available at;
http://cancer.unm.edu/content.aspx?section=intranet&id=43752.

I – Data Safety Monitoring Plan: Overview and Processes

This document provides the Principal Investigator (PI) and research staff of the UNM CC and NMCCA with necessary background information on data and safety monitoring and guidance on NIH required data and safety monitoring.

This DSMP is modeled upon the essential elements as outlined by the NCI. They are as follows:

- ***Monitoring the progress of trials and the safety of participants.***
- ***Plans for assuring compliance with requirements regarding the reporting of adverse events (AEs).***
- ***Plans for assuring that any action resulting in a temporary or permanent suspension of an NCI-funded clinical trial is reported to the NCI grant program director responsible for the grant.***
- ***Plans for assuring data accuracy and protocol compliance, including minimization of risks.***

1. MONITORING THE PROGRESS OF TRIALS AND THE SAFETY OF PARTICIPANTS

Trials are monitored according to the type of sponsor, type of trial and the assignment of potential risks. Monitoring for clinical trials is a continuous, ongoing review of the conduct of the trial, including adherence to study design and documentation of appropriate reporting of related toxicities.

For each protocol and amendment(s) approved, the University of New Mexico Cancer Center/New Mexico Cancer Care Alliance PRMC will review protocol applications for scientific merit and feasibility before authorizing the IRB-of-record approval process initiation. Scientific review will be done by the PRMC prior to submission to the HRRC or an approved external IRB. The Human Research Review Committee (HRRC), the institutional review board of the University of New Mexico, and the Western Institutional Review Board (WIRB) review the protocols for protection of human subject and other ethical issues. Investigator-initiated, peer-review grant supported, and NCI-Cooperative Group studies are submitted to the UNM Human Research Review Committee (HRRC), while all studies with pharmaceutical company support (including investigator-initiated) are submitted to the Western Institutional Review Board (WIRB). The appropriate committee maintains a copy of all reviews of protocols, which may be requested or reviewed by the NCI.

Either the Medical Director of the CPDMI or the NMCCA will review and approve scientific amendments, except those where there may a conflict of interest; in that case, the amendments will be reviewed by the Chair of the PRMC, or in his or her absence, the Vice-Chair of the PRMC. Administrative amendments will be reviewed and approved by the Administrative Director of the CTO or designee.

The PRMC will determine the level of safety monitoring required for each protocol on a case by case basis. For investigator initiated trials that are determined to be of very high risk, the DSMC will monitor patient safety monthly. After this initial review, monthly review by the DSMC will be implemented for a very high risk study.

NCI policy has required that a Data Safety Monitoring Board (DSMB) be in place for all Phase III randomized clinical trials (http://deainfo.nci.nih.gov/grantspolicies/datasafety.htm). This policy has been recently modified, in that there is no longer a blanket requirement for a DSM Board (DSMB) in the cases of low-risk behavioral and nutritional trials. All such trials should include a DSMP, but this may or may not include a DSMB, depending chiefly on the anticipated level of risk to participants. Nor does NIH or NCI policy require that formal DSMB's be constituted for clinical trials other than Phase III. However, for investigator-initiated trials the Data Safety Monitoring Committee will act as or designate a Data Safety Monitoring Board for investigator-initiated phase I-III clinical trial initiated at UNM CC or the NMCCA. The DSMC may designate a field expert to convene a protocol specific Data Safety Monitoring Board.

All studies opened at the UNM CC or NMCCA are assigned a risk level after PRMC review and approval as described in the table below. Most studies at the UNM CC and NMCCA are high risk.

CTO Risk Definition Table

Level of Risk	Explanation	Examples
Low Risk	Study poses no more risk than expected in daily life	Behavioral Studies Nutrition/food supplement Studies Observation Studies MRI Studies Survey/Questionnaire Studies Biological sample acquisition
High Risk	Phase I, II,III, IV therapeutic, palliative or prevention trials that are sponsored by national cooperative groups or NCI/NIH that already include independent appropriate/approved data and safety monitoring plans *Phase I, II, or III therapeutic, palliative or prevention trials sponsored by industry that include appropriate/approved monitoring plans Investigator initiated Phase I, II or III single institution studies that utilize FDA approved agents or agents that have already been the subject of two publications of a clinical trial All recombinant protein vaccine studies	Most cancer treatment studies
Very High Risk	All Phase III investigator initiated multi center trials Phase I studies with agents that have never been used in humans Gene therapies that are not FDA approved for commercial distribution High dose studies All viral, bacterial, or cellular based vaccine studies, regardless of whether or not the vaccine is “live” or “killed”	Implantation of device with an IDE never used before Involves the use of a new chemical or drug for which there is less than 20 patients or no toxicology data in humans A gene therapy study or research involving recombinant DNA molecules (gene transfer) A Principal Investigator initiated multi-center trial Investigator initiated phase III clinical trial Involves the manufacturing of agents on campus Bone marrow support needed after chemotherapy

All protocols will have an annual report which will be drafted and forwarded to the IRB of record for protocol renewal.

Items to be Monitored.

Monitoring Elements and Structure

A clinical study and its components are classified into two (2) monitoring groups; Central Elements and Study Conduct. Central Elements include 1) subject eligibility, 2) consent and 3) data quality. Study Conduct includes accruals, treatment, toxicity and study outcome. This assures that the study progress will be adequately reviewed to provide “real time” monitoring for safety and provide data and information to provide to the DSMC.

Monitoring Frequency

The PRMC assigns the level of risk for each clinical trial. The DSMC provides oversight for safety based on these risk categories.

	Low	High	Very High
PMC continuous review and oversight	HRRC Annual Progress Report	6 month report and HRRC Annual Progress Report	Monthly reports and HRRC Annual Progress Report

Therapeutic intervention:

Phase I – The DSMC continuously monitors all patients for central elements. In addition, for dose escalating trials the DSMC continuously monitors the patients at each respective dose level and the required toxicity evaluation intervals to assure the conduct of the trial complies with protocol design.

Study conduct, timeliness and accuracy of data are monitored regularly for the first 3 patients of the trial (and reported to the PI no later than at the time the third consecutive patient completes course 1) and for one patient per dose level. After the first oversight review, the DSMC will designate the frequency with which the study will be monitored going forward with no less than a quarterly review.

Phase II - The DSMC continuously monitors all patients for central elements. The first two (2) patients enrolled are continuously monitored after the first course of treatment for study conduct. After the first oversight review, the DSMC will designate the frequency with which the study will be monitored going forward with no less than a biannual review.

Phase III – The DSMC functions as the DSMB for UNM CC Investigator Initiated Trials. The DSMC continuously monitors all patients for central elements. Study conduct elements will be monitored regularly for the first 2 patients of the study (and reported to the PI no later than at the time the third consecutive patient completes response evaluation or 6 mos. on study) and for one or more patient per year, estimated to equal at least 10% of total patients accrued. Other protocol endpoints listed as primary objectives (e.g., survival, event-free survival, specific toxicities or quality of life measures) are monitored on an annual basis. After the first oversight review, the DSMC will designate the frequency with which the study will be monitored going forward with no less than a biannual review.

Non therapeutic intervention:

Monitoring is primarily through the principal investigator and research nurse (RN). Central elements will be monitored and reviewed on an annual basis by the DSMC. The conduct of the study and any observed toxicities (including AE and SAE events) are reported in required annual documentation to the IRB.

Multi-site studies

Other Institutions, Investigator Initiated trials in which UNM CC is a participant

Require a summary of the DSMP for the collaborative trial; the DSMC will review the DSMP as part of the initial review process in parallel with review by the IRB. The DSMC will ensure the monitoring by the other Institution meets the minimum requirements of UNM CC DSMP, if it does not the UNM CC DSMC will monitor this study for the UNM CC. Monitoring will be according to the requirements for an institutional study of comparable type, including reporting for AEs and SAEs according to UNM CC standards and through the appropriate channels as the other institution may hold the IND or IDE relevant to the trial.

Trials centered at or led by UNM CC clinical investigators but performed at unaffiliated sites

Requirements are as above based on the Phase of the trial. The DSMC will monitor the unaffiliated site within 6 months of the first protocol entry at the unaffiliated site. Subsequent monitoring will be determined by the DSMC.

Monitoring Determined by Type of Protocol Sponsor

Sponsor: National Institutes of Health

The following types of NCI-sponsored cooperative group trials are currently conducted by UNM CC/NMCCA: American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB), Gynecologic Oncology Group (GOG), Radiation Therapy Oncology Group (RTOG), Southwest Oncology Group (SWOG), Children's Oncology Group (COG), North Central Cancer Treatment Group (NCCTG), National Surgical Adjuvant Breast and Bowel Project (NSABP), Eastern Cooperative Oncology Group (ECOG), and other trials that may be accessed through the Clinical Trial Support Unit (CTSU). Phase I, II and III clinical trials that are sponsored by the NCI Cooperative Groups are monitored by mandated, long-standing and established data and safety monitoring committees at the cooperative group level. These cooperative group studies are not monitored by the UNM CC DSMC, but they are included in the annual internal audits conducted by the Quality Assurance Office of the CTO.

National Institutes of Health R01, R02, and Quicktrial/R21 grant mechanisms provide funding for small pilot, phase I or phase II clinical trials of agents. These grants supporting clinical trials are required to provide specific data and safety monitoring plans to receipt of funding. Studies monitored under a Phase I contract will use the NCI-specified reporting mechanisms. These trials will be monitored by the DSMC, depending upon there level of risk, and they are included in the internal audits conducted by the CTO.

Sponsor: Local, Investigator-Initiated Clinical Trials, Limited Institution Trials
For local, investigator-initiated Phase I, Phase II and Phase III clinical trial protocols, the DSMC will provide continuous monitoring. The data collected for these investigator initiated trials is performed by a Clinical Research Associate (or equivalent position) who is a member of the CPDMI who will generate a report for submission to the DSMC, with a copy to the PI..

Sponsor: Pharmaceutical Company
Protocols sponsored by a pharmaceutical company are monitored by the pharmaceutical company holding the IND; specific arrangements for monitoring are included in the agreement with the sponsoring company and outlined in the DSMP described in the protocol.

For non-therapeutic trials and those trials without significant health or safety risks:
For trials based upon survey research, questionnaires, blood or tissue sampling, observational studies, or limited interventional studies typically addressing research in cancer prevention and control, monitoring is primarily through the principal investigator and research nurse or data coordinator. The CTO monitors all central elements on an annual basis. The conduct of the study and any observed toxicities (including AE and SAE events) are reported in annual documentation to the IRB of record.

Discontinuing Protocol Monitoring Process (es): If a study is closed to accrual or closed to the IRB and no patients are receiving treatment or follow-up evaluations, a notice for discontinuing monitoring and DSMC oversight is required to be submitted from the PI to the IRB of record, with a copy submitted to the Chair of the DSMC. Documentation of the discontinuation is kept in the study regulatory binder.

II. Internal Audit and Quality Assurance

The related processes of monitoring and auditing are integral to assuring both the safety of all subjects participating in any clinical trial, as well as the quality of all data generated.. While similar, they are not identical. Monitoring entails verification of all protocol-required data which is generated by all participants, while auditing is assuring that the appropriate processes are in place to maximize safety and data integrity, and that there is close adherence to the processes. Monitoring focuses upon the study subjects and their outcomes, while auditing focuses upon the behaviors of the site and investigative team.

In line with the NCI's quality assurance requirements, and in accordance with UNM-CC SOPs, when a new site or center is added to either the UNM-UNM CC (a satellite site) or joins the NMCCA, that site will be audited after entering their first subject in a cancer treatment trial, regardless of sponsor. Subsequent audits will be performed annually. Pharmaceutical trials are audited by the protocol sponsor, but cooperative group and investigator-initiated trials will be audited internally, at least annually, at UNM CC and NMCCA sites.

Internal Auditors review three main categories of information: 1) conformance to Institutional Review Board and informed consent requirements, 2) shipping, storage, and use of drugs and other agents, and 3) individual patient cases.

The site prepares for the audit by gathering all source documentation pertaining to the selected case (or cases for subsequent audits). For each selected case, the following records should be available:

- Informed consent documents
- Protocol flow sheets
- Hospital charts
- Physician and research notes
- Outpatient and clinic records
- Correspondence
- X-rays
- Scans
- Other pertinent studies

All records regarding the disposition of investigational drugs, specifically copies of drug orders, return receipts, transfer forms, and the NCI Drug Accountability Records, must be available. The Pharmacy is notified that the auditors will conduct an on-site inspection of investigational agent storage facilities, procedures, and records.

The Principal Investigator or designee for the site, and his/her research staff, are available throughout the audit to answer any questions and help the auditors locate necessary information in the source documents. Source documents are used to verify specific data related to the clinical research trial. The Regulatory Binder and all source documents are available to the auditor. An appointment with the Pharmacist is scheduled if a pharmacy audit is planned or the visit is a site close-out visit.

The internal auditor will verify:

- The informed consent is signed, dated, and on file for the patient.
- The appropriate version of the consent is signed.
- Documentation that confirms the patient met the eligibility criteria.
- Data collected is in compliance with the protocol and is consistent with source documentation. The auditor will identify variation, determine accuracy of endpoint, and compliance to adverse event reporting. In addition, the auditor will confirm that the following regulatory documents are on file:

  IRB approval letters
  IRB letters of annual approval
  IRB approved consent forms
  Copy of IRB assurance
  FDA 1572 Form and curriculum vitae for each investigator
  Site registration approval letters and e-mails
  Laboratory certification when applicable
  Safety reports and memos with appropriate IRB correspondence
  Additional documents as deemed per case

UNM CC Objective criteria are evaluated against source documentation and a Major or Lesser deficiency (as defined by the Cancer Therapy Evaluation Program, CTEP) is assigned to any criteria not meeting compliance.

Major deficiency is defined as a variance from protocol-specified procedures that makes the resulting data questionable. The following are examples of major deficiencies:

- Protocol never approved by IRB
- Expired IRB re-approval
- Informed consent document does not have the elements required by the Code of Federal Regulations
- Patient did not meet all eligibility criteria specified in the protocol
- Pre-entry and entry clinical or laboratory assessments that are missed or obtained outside the protocol specifications
- Reporting errors that affect patient stratification
- Patient's signed consent form missing
- Consent form used was not current IRB approved version at the time of patient registration

- Reportable adverse event not reported to IRB
- Toxicity that would require filling an Expedited Adverse Event Report (AER) was not reported
- Grades, types, or dates/duration of serious toxicities inaccurately recorded
- Incorrect agent/treatment used
- Concomitant medication that is prohibited by the protocol was administered
- Dose deviations (error outside the range of +/- 10%)
- Receipt, use, and disposition of supplied investigational agents cannot be tracked
- NCI Drug Accountability Forms (DARFs) are not maintained
- Tumor measurements/evaluation of status or diseases not performed according to protocol parameters
- Errors were made in reporting endpoints as specified in the protocol
- Recurrent missing documentation
- Numerous transcription errors, without reasonable explanation and corrective action
- Delinquent data submission

A lesser deficiency is one that is judged to not have a significant impact on the outcome or interpretation of the study and is not described as a major deficiency. An unacceptable frequency of a lesser deficiency is treated as a major deficiency in determining the final rating of a component.

If the site is found to have major deficiencies in any of the three categories (Regulatory Compliance, Pharmacy Accountability, and/or Individual Patient Case Records), the site will be required to submit a written response and/or corrective action plan to the UNM CC.

A copy of the internal audit report will be sent to the site to document audit findings, and copies of the audit will be sent to the UNM CC site Principal Investigator, Research Nurse, Data Coordinator, Research Pharmacist and the Regulatory Manager. Offsite audit reports will be forwarded to the UNMCC Principal Investigator.

THE REPORTING OF INTERNAL ADVERSE EVENTS (AEs)

1. Adverse Events (AEs) are events occurring to patients while on study. Further, as defined by the NIH and NCI, an AE is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure. AE documentation is the responsibility of the PI, and any sub-PIs and research nurses who may be participating in the care of the patients. A report is prepared by the PI with the research nurse or data coordinator, as required by regulation and the IRB of Record.

An AE is a term that is a unique representation of a specific event used for medical documentation and scientific analyses. Each AE is graded on the NCI CTCAE scale from 1 to 5 and are defined by three sets of terms, expected/unexpected, serious/non-serious, or unlikely/possibly/probably/definitely attributed to the protocol. Expected AE are those listed as such in the protocol.

Serious AE (SAEs) include toxicities which cause death, are life-threatening, result in new hospitalization, or a prolongation of an existing hospitalization, cause a persistent disability, congenital anomaly, or psychiatric disorder.

Attribution of the AE will be made by the protocol PI in the case of serious or unexpected AE, and by the assigned research nurse in other cases.

AE reporting procedures are specified in detail in each individual protocol, depending on the type of study, the type and severity of the AE, the trial sponsor, the IRB of Record, and existence of an IND.

All events that fall under the definition of serious or unexpected AE including the ones occurring within 30 days following the last treatment date, must be reported to the sponsor within the specified time frame in the protocol and the requirements of the IRB of Record..

For all trials with an external sponsor, internal AE's from UNM CC or other NMCCA sites are to be reported to both the protocol sponsor and the IRB of record. The University of New Mexico IRB policy may be found at http://hsc.unm.edu/som/research/hrrc/hrrc_Guidelines.htm. For investigator-initiated trials, all unexpected Grade 3 and 4 AEs documented for that reporting period (either every 3 or six months) are submitted to the DSMC for review, who then reports to the IRB with the appropriate recommendations to either continue the protocol as is, amend the protocol, or terminate the protocol, for safety reasons. For multicenter trials which are coordinated by the UNM CC, the Regulatory Office also submits copies of all documentation to the Principle Investigators at the participating sites, as well as any feedback documentation generated by the DSMC, the IRB, and subsequent responses by the UNM CC PI. It will be the responsibility of the PIs at the various sites to submit this information on to their respective IRBs.

For trials of an investigational agent for which NCI is *not* the IND holder: The controlling regulations are those of the Food and Drug Administration (21 CFR, Part 312.32: Expedited Safety Reporting Requirements for Human Drug and Biological Products) and are available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.32. They describe the responsibilities of the investigator and the IND holder. Additional sponsor or institutional requirements may be appropriate for specific agents and included in the pertinent protocol sections.

For trials involving commercially available agents (no INDs involved)**:** Serious adverse events that occur with commercially available agents/devices are reported through Food and Drug Administration Medwatch (http://www.fda.gov/Safety/MedWatch/default.htm).

For trials involving Recombinant DNA molecules: In addition to the reporting requirements for investigational agents, investigators should adhere to NIH Guidelines for Research Involving Recombinant DNA Molecules (Gene Transfer). (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html)

Food and Drug Administration reporting requirements of serious adverse events for post-marketing trials of vaccines: Serious adverse events must be reported according to applicable FDA regulations (http://www.fda.gov/cber/vaers/vaers.htm).

For trials involving behavioral or nutritional interventions that do not use an investigational agent: Since there are no standard grading scales for adverse events, 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.

Adverse Event Reporting

EXPECTED EVENT[1]		**UNEXPECTED EVENT[2]**	
Grades 1 - 3	**Grades 4 and 5** **Regardless of Attribution[1]**	**Grades 1– 2** **Attribution of Possible, Probable or Definite**	**Grades 3 - 5** **Regardless of Attribution**
Adverse Event Expedited Reporting NOT required.	Report by phone or email to the IRB of record within 24 hrs of learning of the event. Expedited report to follow within 5 working days. This includes all deaths up to 30 days after the last dose of treatment with an investigational agent regardless of attribution. Any late death attributed to the agent (possible,	Adverse Event Expedited Reporting NOT required. .	Report by phone or email to the IRB of record within 24 hrs of learning of the event. Expedited report to follow within 5 working days. This includes all deaths up to 30 days after the last dose of treatment with an investigational agent regardless of attribution.

EXPECTED EVENT[1]		UNEXPECTED EVENT[2]	
Grades 1 - 3	**Grades 4 and 5** **Regardless of Attribution[1]**	**Grades 1– 2** **Attribution of Possible, Probable or Definite**	**Grades 3 - 5** **Regardless of Attribution**
	probable, or definite) should be reported within 5 working days. Enter the event into Velos within 48 working hours.		Any late death attributed to the agent (possible, probable, or definite) should be reported within 5 working days. Enter the event into Velos within 48 working hours.

[1]The exception to this is expected grade 4 myelosuppression or other grade 4, as specified in each protocol.
[2]These toxicities should always be submitted as part of the study results.

3. Plans for assuring that any action resulting in a temporary or permanent suspension of an NCI-funded clinical trial is reported to the NCI grant program director responsible for the grant. This applies only to NCI sponsored trials.

Any NCI sponsored trial suspended temporarily or permanently will be reported by the PI to the NCI grant program director responsible for the grant within 5 working days. The name and address of the NCI grant program director responsible for the grant must appear on the UNM CC PROTOCOL ABSTRACT form. If CTEP drugs are used in the study, the suspension will also be reported immediately to CTEP. If the suspension is temporary, the NCI and CTEP will also be notified in a timely manner by the PI regarding the resolution of the issues that caused the suspension, and the date that the suspension was lifted. A note to file must document that the NCI (and CTEP, if applicable) has been notified. Any action taken by the HRRC will follow HRRC policy, and be reported to the NCI.

4. Plans for assuring data accuracy and protocol compliance, including minimization of risks.

It is the responsibility of the PI to lead their specific clinical research team according to Good Clinical Practice guidelines. All research project personnel who work with research subjects, data or samples must complete the HRRC Web-Based Training Program, which can be accessed at http://hscapp.unm.edu/hrrc/index.html.

HIPAA training of clinical research faculty and staff is also required and can be accessed at: http://hsc.unm.edu/som/research/HRRC/ . All study personnel must answer a UNM conflict of interest form. UNM Conflict of Interest matters are deliberated by the UNM Conflict of Interest Committee. A "yes" response to the Conflict of Interest questionnaire will require management by this committee and may result in delay in the initiation of the research project. Information about the Conflict of Interest Committee policies and procedures can be accessed at: http://research.unm.edu/coi, and http://www.unm.edu/~ors/pdf_files/unm_forms/COI_Policy.pdf

Additionally, all of the following conditions must be met:

4.1 All protocol participants must be registered in the CTO database.

4.2 If any answer indicates the participant does not completely meet eligibility, a note with the rationale for inclusion must be included in the patient chart by the PI. For NCI sponsored studies, the system does not allow registration of participants with less than complete eligibility.

4.3 The date in the current informed consent document is displayed to ensure only the most current IRB-approved version is used.

4.4 A case report form must be filled to collect data required by the protocol to meet protocol objectives. Consent date, registration date, off study date, and eligibility data are required for all registrants. The current electronic data capture system of the UNM CC must be used for all investigator initiated trials. An accession log will be maintained allowing patient identification by study personnel only. All case report forms to be reviewed by outside personnel will be anonymous. For pharmaceutical trials, the

company case report form will be used, as needed. For cooperative group trials, the case reporting system of the cooperative group will be used. HIPPA rules are implemented per UNM regulations.

4.5 The Quality Assurance Office will retrospectively audit high and very high risk investigator initiated trials and cooperative group studies. A random selection of charts will be chosen for studies based on the UNM CC Annual Audit Plan. Internal audits may occur at higher frequencies as required by the UNM CC Clinical Director, the CTO Medical Director, PRMC, and DSMC.

4.6 Protocol deviations for investigator-initiated trials will be reviewed quarterly. If any trend becomes apparent, a corrective action plan will need to be drawn up and submitted to the Office of Quality Assurance for review and follow up.

Part II – Responsibilities/Processes

Investigator

The PI of each study is ultimately responsible for every aspect of the design, conduct, and final analysis of their protocol. The Principal Investigator is responsible to ensure that:

- Protocol includes the data and safety monitoring plan and procedures for its implementation.
- All studies have a structured adverse event determination, monitoring and reporting system.
- Protocols describe procedures for protection of human subjects.
- All masked studies describe a randomization scheme, and specific criteria and procedures for unmasking. If a DSMB is not proposed, the application should also designate individuals with access to unmasked data.
- In specific cases where an outside agency is the sponsor of the test agent, i.e., holder of the Investigational New Drug (IND) application, the Principal Investigator submits individual adverse event reports to the funding agency (sponsor) in accordance with agency and FDA regulations.
- Regularly submits reports as designated and required by this plan.
- Protocol amendments are submitted per this plan for review prior to IRB submission and approval.

Protocol serious adverse events, adverse events and protocol deviations are submitted to the IRB of Record and the Sponsor of the trial.

The PI is responsible for following all protocol-specific early stopping rules. As the DSMB for UNM CC and the NMCCA, the DSMC will insure that the following early stopping rules will be implemented for intervention protocols based on the guidelines below:

Phase I	Phase II	Phase III
The design is an early stopping rule in itself. No action needed	The two step design will permit reevaluation after completion of the first step. Unless otherwise specified in the protocol, the DSMC will consider closure of the study for unexpected >50% Grade 4 hematologic toxicity and >20% grade 3/4 non hematologic toxicity when patients are treated at the lowest dose level	The protocol must specify the early stopping rules.

-

Clinical Trial Office (CTO)

The UNM CC CTO encompasses the administrative/regulatory and scientific aspects of clinical protocol implementation and management at the UNM CC. The staff of the CTO support the CPDMI, PRMC, PSRS,

and DSM guidelines of the NCI Cancer Center Support Grant. All UNM CC related trials involving human subjects or samples are implemented and managed through this office.

The Director and CEO of the UNM CC is responsible for the CTO, and delegates the day to day operations to the CTO Director and the Medical Directors of the CPDMI, PSRS, PRMC and DSM. The committees that support these activities are the PRMC, the DSMC, PSRS and CPDMI Quality Assurance Committee have quality oversight by the Clinical Research Committee (CRC), which ensures proper review and monitoring of clinical trials has taken place, but does not itself perform that review and monitoring.

The CTO is organized in two (2) components: A regulatory component called *Clinical Protocol Data Management* and *Informatics* (CPDMI) and a scientific component called *Protocol Review and Monitoring System* (PRMS). The CTO supports all essential services necessary to perform clinical research in compliance with all regulations of Good Clinical Practice (GCP).

The ***CPDMI administrative and regulatory activities*** related to data and safety monitoring are as follows;

- ❖ Clinical Research Nurse Office

  - Hires and supports clinical staff responsible for coordinating and implementing studies
  - Reviews proposed protocols as part of disease specific clinical work group for procedural nursing issues
  - Coordinates clinical research activities in compliance with sponsor and regulatory requirements
  - Screens patients for clinical studies
  - Assists with consenting patients to clinical trials
  - Reviews eligibility criteria and implementation of study criteria
  - Assesses patient safety
  - Coordinates study treatment administration
  - Tracks all protocol deviations
  - Conducts patient follow-ups
  - Collects research data
  - Resolves monitoring queries
  - Assists with external and internal audits
  - Tallies patient demographics and outcomes
  - Prepares study initiation meetings

- ❖ Regulatory Office

  - Assembles all documents needed to open a study
  - Initiates confidentiality and Disclosure Agreements
  - Coordinates IRB applications and correspondence
  - Processes adverse events
  - Tracks study contract
  - Coordinates protocol continuing review and reports
  - Coordinates protocol amendments
  - Implements study terminations
  - Retains training logs, CLIA's and curriculum vitae
  - Retains document storage, conflict of interest records and communication with all UNM, NMCCA, Affiliates, cooperative groups, NCI, sponsors, and FDA regulatory committees or spokesperson
  - Arranges site initiation meetings

- ❖ Informatics Support Office

  - Manages hardware and software to support regulatory and scientific components
  - Provides continuous training and support for staff

- Provides data management support
- Manages UNM CC CTO internet and intranet website

❖ Investigational Pharmacy

- Reviews protocol for study drug concerns
- Receives investigational and/or study drugs
- Maintains drug accountability
- Verifies ordering physician is on the 1572 form
- Stores, prepares and dispenses study drugs

❖ Quality Assurance Office

- Compiles data for monitoring as defined by the DSMP and reports the results to the DSMC.
- Completes second review of eligibility for off site enrollments to investigator initiated and cooperative group protocols.
- Maintains Standard Operating Procedures and coordinates annual review.
- Conducts ongoing retrospective and focused audits on selected protocols
- Reviews all unexpected deaths on study for investigator initiated trials and submits to DSMC for action
- Coordinates internal and external audits
- Receives and reviews results of external audits and works with Principal Investigator and CTO Director to take appropriate action
- Prepares or coordinates formal external triennial audit responses with cooperative groups
- Provides education based on audit results
- Provides quarterly report of auditing activity to the UNM CC Director, CTO and NMCCA Executive Director and Medical Director, and the Chairs of the PRMC and DSMC.

❖ Data Safety Monitoring Committee (DSMC)

Appointments- The Chairperson of the DSMC will be appointed for a three year term, renewable once, by the UNM CC Director and CEO. Committee members will include at a minimum a Committee Chairperson, four members who are active investigators appointed for a two year term renewable twice, a biostatistician, and six (6) permanent members: the Medical Director of the NMCCA, the Medical Director of the UNM CC CPDMI, UNM CC CTO Nurse Manager, the Chairperson of the PRMC, the Human Protection Specialist, and the CPDMI Manager. One of these members will act as Vice-Chairperson and serve three years. Any additional members may be requested by the Chairperson, as needed.

Authority- The DSMC will act as the Data Safety Monitoring Board for studies approved by the PRMC unless otherwise specified by this plan or the IRB of record. The DSMC will review and monitor all study progress for investigator-initiated trials, or those designated by the PRMC. If appropriate, the DSMC will designate and monitor corrective action(s) based on review outcome. The DSMC will have the authority to amend and/or terminate protocols based upon issues of safety. The Chairperson may call an ad-hoc committee meeting at any time to solve on-going problems.

Confidentiality**:** All DSMC members must abide by the Confidentiality Agreement they signed upon hire by the University of New Mexico or consistent with their participation agreement with the New Mexico Cancer Care Alliance.

Conflict of Interest: Abstention from monitoring review or voting by committee members will be accepted only if the committee member has a conflict of interest and/or a lack of expertise in the

scientific subject of the protocol. A committee member who is an investigator on a study will be asked to rescues him/herself from the review process.

Monitoring Review: The DSMC will review the reports of monitoring of the Central Elements and Study Conduct. The frequency of the review by the DSMC is defined by this DSMP.

Study Progress prior to IRB Continuing Review: The DSMC will have an option of two levels of review; expedited and full based on the following guide;

Full Review. This will be performs for all investigator-initiated High Risk and Very High Risk trials. Staff compiles the study review forms (Addendum G, DSMC Interim Review and Report Form) and forwards to two (2) members of the committee for review. One reviewer must be a physician. If a committee member cannot review the protocol report within three (3) working days, the committee member must notify the appropriate staff within one (1) working day. If a committee member does not respond to 80% of the request for reviews, that member can be removed from the DSMC and his/her department Chairperson will be notified of the decision. Abstention from reviewing or voting by committee members will be accepted only if the committee member has a conflict of interest and/or a lack of expertise in the scientific subject of the protocol.

Staff will compile the results of the member reviews and forward to the Chairperson of the committee.

The Chairperson reviews the committee decisions and if there are no outstanding issues signs the report. The staff forwards the report to the PI, Research Nurse, and Regulatory Coordinator.

Expedited Review. This will be performed for all Low Risk investigator initiated Low Risk trials. Staff will compile the studies eligible for expedited review on a monthly basis for review by the Chairperson. If no issues are found, the Chairperson will sign the Disposition Letter, approving the study and return it to the staff. The Chairperson has the right to request a full review, call a committee meeting or request other action if the Chairperson finds the expedited review insufficient.

Review Outcome: The DSMC will make the following recommendation;

- **Approved** – Enrollment may continue
- **Close to accrual** – Close enrollment
- **Close study –** No patients on active treatment or follow up or other criteria reviewed
- **Temporarily Close to Accrual –** delinquent progress report

The DSMC has authority to requests additional information to be provided to the committee, an internal audit of patient record(s) and regulatory information, or protocol amendment(s).

Additional requested items may be;

- Exceptions in eligibility or treatment
- Best response to treatment for each patient, for Phase II and III studies
- Treatment arm for each patient, for Phase III studies
- Study and survival status of each patient
- Results of any interim analyses required by the protocol
- Copies of abstracts or papers written using study data

The PI will be required to provide any additional information within a specific time frame as determined by the committee. Staff will follow up and provide the Chairperson with the required

information. The Chairperson will review the information and uphold the review outcome or make further recommendations.

All DSMC decisions are conveyed in writing to the Investigator (Addendum H, DSMC Disposition Letter). DSMC will state specific reason(s) for the decision. Principal Investigators may appeal DSMC decisions in writing (Addendum I, DSMC Appeal) to the DSMC Chairperson within five (5) working days. The Principal Investigator must respond to each reason(s) in the decision.

Appeals will be electronically distributed to two (2) members of the DSMC which were not involved with the original review. Reviewers will have five (5) working days to complete their review and return comments to the DSMC Chairperson. The DSMC Chairperson will convey the results in writing to the Principal Investigator. All appeal decisions will be final.

Temporary or permanent suspension of any NCI-sponsored clinical trial by either the DSMC or the HRRC will be reported immediately to the NCI project manager for that trial. If CTEP drugs are used in the study, the suspension will also be reported immediately to CTEP. If the suspension is temporary, the NCI and CTEP will also be notified in a timely manner regarding the resolution of the issues that caused the suspension, and the date that the suspension was lifted.

The committee will meet at least biannually to review processes and receive training as needed

Corrective Action Item(s) Request and Disposition: Corrective action item(s) may be requested based on review findings. Any review finding that results in a protocol deviation requires correction action. The reviewer provides a recommendation for corrective action on the DSMC Reviewer Form. The DSMC Coordinator compiles the reviewer findings for the Chairperson. The Chairperson reviews and approves requested corrective action. The key members of the Research Team receive a copy of the DSMC disposition with the required corrective action.

Corrective action items are classified as Administrative or Scientific based on the following criteria:

Corrective Action Criteria for Investigator-Initiated Trials

Administrative – issues reflecting;	**Scientific – items reflecting;**
All Low Risk trials	Research Objectives
Nominal changes to protocols	Consent/Eligibility
Data Quality	Treatment/Response
Accrual Targets	Adverse Events
DSMC Chairperson	Full DSMC

Corrective action items are followed by the DSMC Coordinator. A follow up disposition is completed when a corrective action item(s) is completed or delinquent and reviewed by the appropriate individual per the above criteria. The disposition is forwarded to the key members of the Research Team and the HRRC. Documentation is maintained in the Office of Quality Assurance and the study regulatory manual in the CTO.

Training Grants

Certain types of NCI career and training awards may support clinical trials, directly or indirectly. NCI's DSM policy covers those career and training awards in which the trainee has direct responsibility for conduct of the clinical trial or in which award funds directly support the trial. Responsibility for compliance with NCI's DSM policies rests with the grant recipient; this may be either the trainee or the training program director, depending on the award (individual versus institutional). Trainees in a mentored career program should consult with their mentors about adapting or designing suitable DSM plans for their clinical trials. In most cases the trainees will be in a mentored stage of their career and will lack the experience needed to provide appropriate oversight of the trial. The DSM plan must therefore clearly identify the senior individual responsible for monitoring the trial and the function of the trainee in this process.

- For institutional career development programs (e.g., K12, R25T) in which clinical trials are an integral part, applicants should provide with their application a "Special Institutional Statement Regarding Human Subjects Research under K12 or R25T Support". This statement must be provided to NCI Program staff for evaluation and approved before the initial grant award can be issued, and submitted for evaluation and approval with each "Application for a Continuation Grant."

For individual career development awards in which the grantee has direct responsibility for trial conduct or in which award funds directly support the trial, the DSM plan covering the trial may NOT be an institutional plan. The DSM plan must be tailored specifically to the clinical trial.

A DSM plan does not need to be provided for individual career development awards in which:

The trial is a component of an NIH Cooperative Group trial;

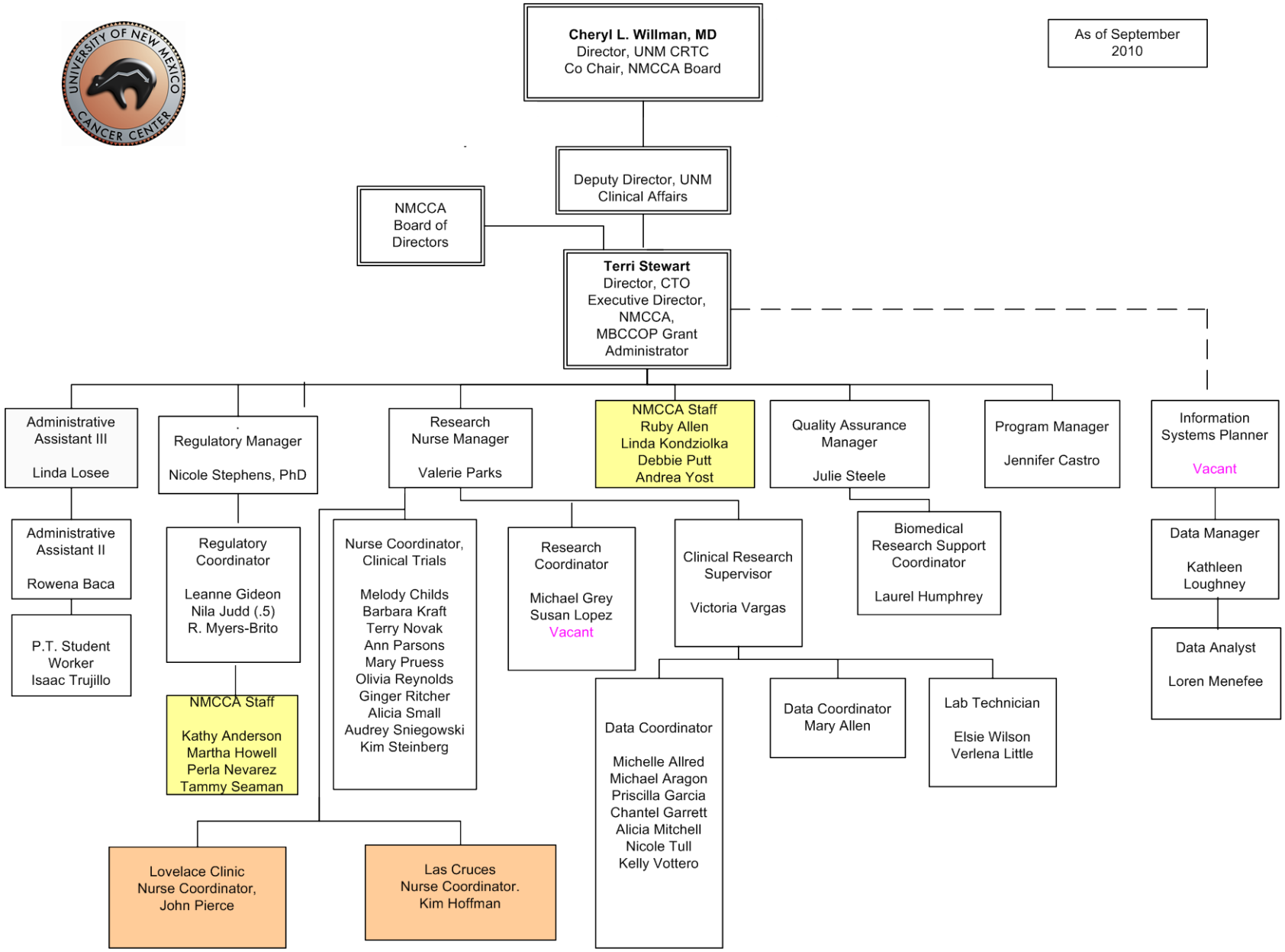
The trial is a CTEP-supported protocol;

The trial is being partially or completely supported by an investigator-initiated NIH R-grant, with an approved DSM Plan.

For individual career development awards in which a clinical trial will be conducted that does not require the submission of a DSM plan, the grantee must submit for evaluation a letter to NCI program staff describing their situation and explaining why a DSM plan is not needed. This letter must be co-signed by the institutional official authorized to evaluate issues pertaining to data safety and monitoring; and, in the case of mentored awards, by the grantee's mentor.

- If the clinical trial is not to be started immediately upon award of an individual career development award but will follow after a considerable lapse of time (years), submission of a DSM plan to NCI for approval may be delayed until the nature of the trial is clear and its initiation is in the near future. This will ensure that the DSM plan suits the needs of the trial.

- For NCI career development awards for established investigators (K05, K24), a DSM plan does not need to be provided. However, a Restriction term will be included in each Notice of Grant Award requiring that the grantee remain in compliance with the NCI's policy on data and safety monitoring throughout the project period.


Cheryl L. Willman, MD
Director, UNM CRTC
Co Chair, NMCCA Board
As of September 2010
Deputy Director, UNM Clinical Affairs
NMCCA Board of Directors
Terri Stewart
Director, CTO
Executive Director, NMCCA, MBCCOP Grant Administrator
Administrative Assistant III
Linda Losee
Regulatory Manager
Nicole Stephens, PhD
Research Nurse Manager
Valerie Parks
NMCCA Staff
Ruby Allen
Linda Kondziolka
Debbie Putt
Andrea Yost
Quality Assurance Manager
Julie Steele
Program Manager
Jennifer Castro
Information Systems Planner
Vacant
Administrative Assistant II
Rowena Baca
P.T. Student Worker
Isaac Trujillo
Regulatory Coordinator
Leanne Gideon
Nila Judd (.5)
R. Myers-Brito
NMCCA Staff
Kathy Anderson
Martha Howell
Perla Nevarez
Tammy Seaman
Nurse Coordinator, Clinical Trials
Melody Childs
Barbara Kraft
Terry Novak
Ann Parsons
Mary Pruess
Olivia Reynolds
Ginger Ritcher
Alicia Small
Audrey Sniegowski
Kim Steinberg
Research Coordinator
Michael Grey
Susan Lopez
Vacant
Clinical Research Supervisor
Victoria Vargas
Biomedical Research Support Coordinator
Laurel Humphrey
Data Manager
Kathleen Loughney
Data Analyst
Loren Menefee
Data Coordinator
Michelle Allred
Michael Aragon
Priscilla Garcia
Chantel Garrett
Alicia Mitchell
Nicole Tull
Kelly Vottero
Data Coordinator
Mary Allen
Lab Technician
Elsie Wilson
Verlena Little
Lovelace Clinic
Nurse Coordinator,
John Pierce
Las Cruces
Nurse Coordinator.
Kim Hoffman

Addendum B

COMMITTEE MEMBERSHIPS

PROTOCOL REVIEW COMMITTEE MEMBERSHIP

NAME	POSITION	EXPERTISE
Julie Bauman, MD	Committee Chair – UNM Cancer Center	Oncology, Head & Neck
Melanie Royce, MD, PhD	Vice Chair – UNM Cancer Center	Oncology, Breast Cancer
Malcolm Purdy, MD	Medical Director, NMCCA	Community Physician, Hematology/Oncology
Dennie Jones, Jr., MD	Medical Director, CPDM	Oncology, Development, Lung Cancer
Valerie Parks, RN	Research Office Nurse Manager, CPDM	Clinical Trials Management, Nursing
Bernard Agbemadzo, MD	Member, Presbyterian Health Care Services	Community Physician, Hematology/Oncology
Lori Dopps, Ph.D	Member, UNM Cancer Center - Pharmacist	Pharmacy, Pharmacology
Elizabeth MacGuire, MD	Member, Albuquerque VAMC	Community Physician, Hematology/Oncology
Ed Bedrick, Ph.D	Member, UNM Cancer Center – Statistician	Statistician
Christine A. Stidley, Ph.D.	Member, UNM Cancer Center – Statistician	Statistician
Sang-Joon Lee, Ph.D.	Member, UNM Cancer Center – Statistician	Statistician
Karen LoRusso, MD	Member, New Mexico Cancer Care Associates	Community Physician, Hematology/Oncology
Karen Finkelstein, MD	Member, Southwest Gynecologic Oncology	Community Physician, Gynecologic Oncology
Teresa Rutledge, MD	Member, UNM Cancer Center	Gynecologic Oncology
David Garcia, MD	Member, UNM Cancer Center	Hematology
Claire Verschraegen, MD	Member, UNM Cancer Center	Oncology: Melanoma, Sarcoma and Rare Cancers, Drug Development, Gynecologic Oncology
Lesley Lomo, MD	Member, UNM Health Sciences Center	Pathology
Steven Eberhardt, MD	Member, UNM Health Sciences Center	Radiology
Nicole Stephens, PhD	Member, UNM Cancer Center	Basic Science
Thomas Schroeder, MD	Member, UNM Cancer Center	Radiation Oncology
Stuart Winter, MD	Member, UNM Cancer Center	Pediatric Oncology

DATA SAFETY MONITORING COMMITTEE

NAME	POSITION	EXPERTISE
Carolyn Muller, MD	Committee Chair	Gynecologic Oncology
Elizabeth McGuire, MD	Committee Vice Chair	Community Physician, Hematology/Oncology
Dennie Jones, Jr., MD	Medical Director, NMCCA and CPDM	Oncology, Drug Development, Lung Cancer
Sang-Joon, Lee, PhD	Member, UNM Cancer Center	Statistician
Valerie Parks, RN	Research Office Manager, NMCCA and CPDM	Clinical Trials Management, Nursing
Nicole Stephens, PhD	Manager, Regulatory Affairs, NMCCA and CPDM	Administrator, Regulatory Affairs
Julie Steele, BA, CCRC, CPHQ, LPN	Human Protections Specialist, Quality Office	Administrator, Quality Assurance
Richard Heideman, MD	Member, UNM Cancer Center	Pediatric Oncology
Robert Quinn, MD	Member, UNM Cancer Center	Orthopedic Oncology
Melanie Royce, MD	Member, UNM Cancer Center	Oncology, Breast Cancer
Amy Tarnower, MD	Member, UNM Cancer Center - Lovelace	Community Physician, Hematology/Oncology
Claire Verschraegen, MD	Member, UNM Cancer Center	Oncology: Melanoma, Sarcoma and Rare Cancer, Drug Development, Gynecologic Oncology
Debbie Winklejohn, RN	Member, Research Nurse Hematology Oncology Associates	Clinical Trials Management, Nursing
Karen Finkelstein, MD	Member, Southwest Gynecologic Oncology Associates	Community Physician, Gynecologic Oncology