

USC Norris Comprehensive Cancer Center

Part of the Keck School of Medicine of USC

CLINICAL INVESTIGATIONS SUPPORT OFFICE – MULTI-SITE COORDINATING CENTER (CISO- MCC)

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Abbreviations

AO: Affiliate Organizations
AE: Adverse Event
CDA: Confidentiality Disclosure Agreement
CIC: Clinical Investigations Committee (Scientific Review Committee)
CISO: Clinical Investigations Support Office
CRF: Case Report Forms
CTCAE: Common Terminology Criteria for Adverse Events
CTO Clinical Trials Office at USC (Budgets and Contracts)
CTEP: Clinical Trials Evaluation Program
DARF: Drug Accountability Report Form
DCG: Department of Contracts and Grants
DHHS: Department of Health and Human Services
DLT: Dose-limiting Toxicity
DSMC: Data Safety Monitoring Committee
EDC: Electronic Data Capture
FDA: Food & Drug Administration
FWA: Federal Wide Assurance
GCP: Good Clinical Practice
HIPAA: Health Insurance Portability and Accountability Act
IB: Investigator's Brochure
ICH: International Council on Harmonization
IND: Investigational New Drug
IRB: Institutional Review Board
LAO: Lead Academic Organization
MCC: Multi-site trial Coordinating Center
NCCC: Norris Comprehensive Cancer Center
NCI: National Cancer Institute
NIH: National Institutes of Health
MRI: Magnetic Resonance Imaging
OHRP: Office of Human Research Protections
ORRP: Office of Responsible Research Practices
PI: Principal Investigator
QAC: Quality/Auditing Committee
SAE: Significant Adverse Event
SOP: Standard of Practice
SUSAR: Significant Unexpected Serious Adverse Reaction
UP: Unanticipated Problem
USC: University of Southern California

1 MULTI-SITE COORDINATING CENTER TRIALS

This manual documents the policies of Norris Comprehensive Cancer Center (NCCC) Clinical Investigations Support Office (CISO) Multi-site trial Coordinating Center (MCC). It applies to all NCCC- led protocols managed by the Clinical Investigations Support Office (CISO) that include at least one external participating site. This manual addresses protocol compliance according to the Office of Responsible Research Practices (ORRP), the International Conference on Harmonization (ICH) Good Clinical Practice, and the Food & Drug Administration (FDA) and Health & Human Services (HHS) regulations & guidance.

The NCCC-CISO expects all external site investigators to comply with appropriate regulatory, protocol, and data collection requirements. The MCC has developed this policy and procedure manual to provide standardization of research practices and consistency in multi-center clinical trial activities.

- This manual must be read, and followed by the NCCC Principal Investigator (PI) before the PI may proceed with opening a multi-center trial managed by the NCCC-CISO.
- This manual must be read and followed by its entirety by external participating sites before the site will be activated to enroll patients in an NCCC-CISO multi-center trial.

NOTE: The program and manual do not relate to any of USC Norris's affiliate or component sites under the NCI Lead Academic Participation grant. This manual does not apply to trials fielded under the UM1 Lead Academic Organizations (LAOs), Affiliate Organizations (AOs), or sites participating in NCCC protocols under the UM1 grant.

1.1 Multi-site trial Coordinating Center Program (MCC) Overview

The mission of the MCC is to facilitate NCCC Principal Investigator oversight of USC-led, investigator-initiated, multi-center trials. The goal of the program is to ensure compliance with local, state, and federal regulations, in addition to ensuring protocol and contract compliance.

The MCC performs a variety of functions, including:

- Ensuring multi-center language is inserted into protocols through use of the boilerplate protocol template
- Performing external site qualification and approval
- Facilitating sub-contracts and budgets in coordination with the relevant entity at USC
Acting as primary CISO-MCC contact for external sites
- Distributing protocol and associated documents to external sites
- Performing initial protocol training for external sites enrollment
- Verifying eligibility, registering, and randomizing external site study participants
- Training external sites on the relevant databases such as USC OnCore® database, USC CAFÉ database, Medidata RAVE® database, or paper case report forms

- Facilitating response to external site patient management inquiries
- Reviewing quality and querying external site data
- Processing external site serious adverse events and protocol deviations
- Monitoring data for safety, accuracy, trends, and reporting requirements including work with NCCC DSMC and QAC
- Coordinating and hosting mandatory protocol data and safety review teleconferences
- Ongoing regulatory document collection from external sites, as appropriate
- Facilitating auditing and monitoring of external sites
- Executing the decision of the USC IRB, DSMC, and CIC to close, suspend and terminate protocols

2 RESPONSIBILITIES OF THE NCCC

2.1 Preparing for Adding External Participating Sites to NCCC-CISO Protocols

The PI of the trial will notify CISO of the desire to field a multi-site trial using the CISO Multi-Site Coordinating Center (CISO-MCC), preferably at the time of concept development or no later than the time of the Clinical Investigations Committee (CIC) review. The PI will provide verification there is adequate funding to support the trial. The protocol may not be rewritten or modified by any other site other than the NCCC. Once the trial has received CIC approval it is recommended the PI meet with CISO Leadership and CTO (Clinical Trials Office) or DCG (Division of Contracts and Grants) to ensure the following requirements are reviewed and met:

1. Confidentiality Disclosure Agreements are sent and executed by the proposed external sites.
2. Sponsors are supportive of the multi-site concept and the prime agreement does not exclude the involvement of external participating sites.
3. Sponsor will confirm the investigational agent will be shipped directly to the external site by the pharmaceutical company or their designee. The MCC will obtain necessary drug ordering forms and assist in coordinating this effort.
4. The MCC will work with the NCCC PI to ensure that all required protocol language for multi- center trial management is incorporated into the protocol document. Some of these items may also be found the negotiated contract.
 - a) Patient registration and randomization procedures for external participating sites
 - b) Investigational agent ordering and distribution details for each USC and external sites
 - c) Data submission requirements, which includes data entry/submission frequency and query resolution for external participating sites
 - d) Adverse Event (AE) reporting requirements, including AE submission, evaluation, and review for each USC and external sites
 - e) Serious Adverse Event (SAE) reporting requirements for USC and external sites
 - f) Protocol Violation reporting requirements

- g) Data & Safety Monitoring and Auditing plans, including frequency and procedures for USC and external sites

5. Review and completion of the checklist for external sites.

2.2 External Site Selection

The MCC will meet with the NCCC PI to create a study-specific PI Checklist for External Sites. The MCC will then send the form to be completed by all external sites identified by the NCCC PI as potential collaborators. The completed *Site Qualification Form* will be reviewed by the MCC and NCCC-CISO Leadership. Input from the USC PI and Disease Group Leader will be obtained, as needed. Site approval to participate will be based on whether defined minimum criteria are met, including documentation. Minimum criteria to be met includes, but is not limited to, the site's demonstrated ability to enroll to the trial and planned accrual goal, documentation of key SOPs, documentation of pharmacy capability, documentation of study team qualification, and historical compliance while participating in other NCCC led clinical trials (where applicable). Following the external site review, notice of the outcome will be sent via email to the Principal Investigator of the trial and the external site.

For sites that do not meet essential qualification requirements, the NCCC PI may seek resolution, if the external site is still a desired collaborator. If after the initial review, the NCCC PI believes that the site has met the qualifications, he/she may request the MCC to re-send the *Site Qualification Form* to the site. The MCC will re-evaluate the site to determine whether minimum criteria are met. Formal notification of qualification status will be re-issued to the NCCC PI and the external site.

2.3 Site Activation Requirements

In addition to working with the CTO to obtain an executed Confidentiality Disclosure Agreement (CDA) prior to protocol document sharing, the MCC will distribute final approved protocol documents to each approved external participating site. In situations of multi-center trial collaboration during protocol writing, the protocol may be distributed if an executed CDA with the site is on file and the protocol has been clearly & legibly watermarked with "DRAFT: DO NOT SUBMIT TO IRB." It must be communicated to the external site that the protocol must not be submitted to any of the external site reviewing bodies (SRC, IRB, etc.) until after USC has received all appropriate final approvals.

The MCC will ensure each external site is affiliated with a local IRB that has a Federal Wide Assurance (FWA) of compliance on file with the Office of Human Research Protections (OHRP), Department of Health and Human Services (DHHS).

- Obtain the external site's laboratory normal ranges prior to site initiation for review.
- Ensure that all involved external site research personnel are approved to be involved with the research and will collect all essential regulatory documents from the external site.

- Confirm a fully executed sub-contract is in place between the appropriate USC entity (USC Clinical Trials Office or Dept of Contracts and Grants) and the external site.
- Review and approve the external site informed consent document prior to local IRB submission. The MCC will also ensure the external site has obtained local IRB approval of the most current version of the protocol.
- Provide and document initial protocol training for the external site.
- Alert the NCCC-CISO ClinicalTrials.gov Administrator to upload the external site contact information and update the site status on the website.

Once all site initiation requirements have been met the site will be issued a site number. This number will be used on all communications and registrations from the external site.

2.4 Active Protocol Management

The MCC assumes responsibility for coordinating study-specific communication and information once the protocol is open at the external site. These activities include the following with detailed information following:

- General Information: In collaboration with the NCCC PI, the MCC will regularly communicate the status of overall study accrual, enrollment availability, and cohort updates, including cohort closures, openings, and slot availability. This information will be communicated as indicated during the mandatory study data and safety review teleconferences. Updates will be provided via email more frequently, as needed.
- Regulatory: The MCC will assure that relevant IRB correspondence and study status changes are communicated to all external sites.
- Teleconferences: The MCC and USC PI will coordinate and host mandatory study data and safety review teleconferences. Each participating site is required to ensure at least one study team member attends each teleconference to provide updates on the status of active study participants at the respective site. The frequency of trial teleconferences will be determined with the PI. If there is inconsistent participation from one of the sites, the information will be discussed with the USC PI for possible suspension. Appendix I holds a sample agenda for the teleconferences.
- Eligibility and Registration: The MCC will review and verify eligibility and centrally register and randomize (if applicable) all external site study participants.
- Training: The MCC will provide access to and general training on all relevant databases for external site coordinators to enter data directly. The use of electronic databases is usual and customary. In the rare case when paper case report forms are indicated, the MCC will create these forms. The MCC will facilitate preparing study data for review by the NCCC PI.
- Database(s): Case Report Forms (CRF) will be in a standardized format. Protocol specific CRFs will be provided, and the schedule for submitting them to the MCC will be stated in each protocol or contract. Unless otherwise specified, all study data will be due within two weeks after completion of each cycle or visit. This parameter will be specified on the study initiation teleconference.

- Significant Adverse Event Reporting: Significant Adverse Event (SAE) reporting is addressed in detail in Sections 9 and 11.
- Dose Modifications/Dose Limiting Toxicities (DLT):
 - Dose Modifications are found in the protocol document. Updates needed based on Serious Adverse Events will be disseminated through Action Letters and/or main site IRB-approved protocol amendments.
 - Dose Limiting Toxicities: In the event of a medically significant toxicity warranting a change, hold, or limit placed on the investigational agent dose for all patients on the applicable dose level, the MCC will notify all sites via email within 24 hours after confirming with the NCCC PI. All participating sites will be required to respond to the email notification to acknowledge receipt. The MCC will follow-up with the applicable participating sites within 5 business days from the original notification to confirm that all patients on treatment have been notified and the dose limitation has been applied.
- Auditing: The MCC and NCCC Audit Team will perform remote auditing. Please refer to section 12 for further details.

3 RESPONSIBILITY OF THE NCCC PRINCIPAL INVESTIGATOR

The NCCC Principal Investigator (PI) is the physician who assumes full responsibility for the integrity of the research data. The PI is responsible for adhering to the protocol, ensuring subject safety is not compromised, and the data is accurate. The PI may delegate some responsibilities as allowed per institutional and NCCC-CISO policies. However, the PI maintains ultimate responsibility for the conduct of the study and the coordination, development, submission, and approval of the protocol and all subsequent amendments.

The PI must maintain clear communication lines with NCCC-CISO and MCC staff to facilitate timely submission and approval of protocol documents by all applicable approval agencies. There will be only one active/current version of the protocol. Every external participating site is required to obtain approval of the most current version of the protocol. The MCC will assist the PI in ensuring that all external sites are meeting the specific responsibilities noted in Section 3.1 below.

3.1 Specific Responsibilities

- Coordinate all protocol activities with the assistance of the assigned NCCC-CISO study team and the MCC
- Provide oversight of study conduct, subject safety, and data quality and accuracy
- Ensure that all involved research personnel, including external site personnel, are approved to be involved with the research
- Monitor protocol progress and ensuring that external site investigators comply with their reporting responsibilities
- Review study data to ensure protocol compliance
- Monitor accrual to the study and stopping the study when the requirements of the study design have been fulfilled
- Collaborate with the biostatistician for study analysis, and leading the research team in preparation of reports and publications.

3.2 Safety Related Information

- Review all serious adverse events including those received from external sites, to assure the safety of the subjects
- Review all IND letters and safety reports, forwarding these to the NCCC-CISO Regulatory Manager and the MCC, and indicating whether the toxicity profile in the informed consent needs to be modified as a result of any new safety related information
- Ensure a report of all safety related AEs are submitted to the USC DSMC within 24 hours
- Ensure all safety related AEs are submitted to the FDA or other external reporting agencies as indicated by the protocol
- Initiate appropriate actions when subject safety is at risk

4 RESPONSIBILITIES OF THE EXTERNAL SITE INVESTIGATOR

An external site investigator of an NCCC-CISO protocol is a physician who participates in clinical trials conducted by the NCCC-CISO. External site investigators must be board certified or have equivalent international postgraduate qualifications in radiation, surgical, or medical oncology and must have a certificate of completion of human subjects' protection training and HIPAA.

The external site agrees to meet the requirements outlined below.

4.1 Regulatory Requirements of the External Site

- Demonstrate compliance with all local, state and federal regulatory requirements
- Follow NCCC-CISO policies and procedures for conducting NCCC-CISO multi-center clinical trials.
- Share internal standard operating procedures (SOPs) with the MCC when in conflict with NCCC-CISO policies and procedures in order to ensure compatibility.
- Submit to the MCC all essential regulatory documents, IRB approval letters and IRB approved informed consent documents prior to site activation (Appendix D)
 - NOTE: Delegation Authority Logs must be submitted no later than 30 days after site activation
- Notify the MCC within 30 days of adding new investigators and/or research personnel to the study
- Notify the MCC within one week of internal protocol status changes (SRC approval, IRB approval, request for closure to accrual, etc.)
 - NOTE: External sites are permitted to close protocols to accrual independently and are required to notify the MCC of this decision within five business days. Complete study closure must be preceded by a site closure visit which ensures all data requirements have been met.

4.1.1 Informed Consent Documents of the External Site

- Ensure that the University of Southern California is listed in study-related informed consent documents and HIPAA consent forms (if separate)
- Submit the initial informed consent document to the MCC for review and approval at least one week prior to planned local IRB submission
- Notify the MCC of any local protocol or consent modification requests. Participating sites may not amend the protocol or consent independently. All consents must be submitted to the MCC for review and approval prior to external site IRB submission and at least one week prior to planned local IRB submission

4.1.2 Local IRB Approvals for the External Site

- Ensure timely submission and approval of annual renewals to the local IRB (minimally within 365 days of previous approval or prior to expiration date)
- Ensure timely submission of amendments and obtaining local IRB approval within 90 days of receipt of documents from the MCC

4.2 Subject Enrollment at the External Site

- Accrue a minimum number of subjects agreed upon to meet protocol objectives
- Informing subjects or their representatives that agents are being used for investigational purposes
- Obtain voluntary, written informed consent of subjects or their authorized representatives, using the most recently IRB-approved informed consent form
- Document subject eligibility and maintaining accurate case histories designed to record all observations and other data pertinent to each subject
- Submitting complete eligibility documentation to the CISO-MCC for review, approval and central registration.
- Agree not to permit any exceptions to eligibility criteria.
- Agree to not institute protocol specific treatment prior to registration with the CISO-MCC.

4.3 Data & Safety Information for the External Site

- Submit accurate and complete data to the MCC within 2 weeks of completion of each protocol cycle, or as otherwise stated within the protocol or sub-contract
- Ensure accurate study drug records are maintained
- Report all SAEs to the MCC according to the protocol and to the local IRB, all applicable reporting agencies, and sponsors per local and institutional policies and procedures

4.4 Auditing & Monitoring at the External Site

- Prepare for audits by making available all source documents, research records, drug accountability record forms, subject registration lists, screening logs, deviation logs, and other documents as requested prior to scheduled audit dates. Alternatively, external sites may choose to provide hard-copy paper documents or access to local electronic medical records for remote auditing and monitoring by the NCCC Audit Team.

4.5 Non-Compliance at External Sites

- Failure to send applicable safety reports to the local IRB per local policy may result in site accrual suspension and/or other corrective action measures by the USC PI.
- Failure to send SAE reports to the MCC and/or the local IRB of record (per local policy) may result in site accrual suspension and/or other corrective action measures by the USC PI.
- Each site must provide the CISO-MCC with a copy of their Federal Wide Assurance (FWA); failure to provide the FWA on file with the Office for Human Research Protection (OHRP) of the NIH may delay site activation and “open to accrual” until the assurance is received by the MCC.
- A trend of failure to notify the MCC in a timely fashion of new investigators and/or research personnel involved with the study may result in site accrual suspension.
- Failure to meet the 90-day deadline for amendment approval by the local IRB may result in site accrual suspension until the amendment is approved. Should failure to meet the 90-day deadline become a trend, the site may be permanently closed to accrual by the USC PI.
- Failure to submit data within protocol- or contract-defined timelines may result in external participating site accrual suspension until data is complete and current. Should failure to meet data submission deadlines become a trend, the external participating site may be permanently closed to accrual by the USC PI.
- External sites are responsible for following the protocol at all times. Serious protocol non-compliance may result in site accrual suspension. The site must submit a corrective action plan to address and remediate the non-compliance. Should failure to comply with the protocol become a trend, the external site will be permanently closed to accrual by the USC PI.
- All accrual closures/holds are effective immediately upon verbal notification. Email confirmation will follow. IRB submissions and approvals will be requested within 30 days.

5 IRB APPROVAL

Research involving human subjects must meet the requirements of the federal regulations for human subjects protection as detailed in the Code of Federal Regulations (CFR) sections 45, 46, 21, 50 and 56 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>). An IRB must review and approve human subject research activities to ensure compliance with all applicable local, state, and federal policies and regulations.

All NCCC-CISO protocols and informed consents will undergo review and approval by the IRB of record prior to distribution to external sites. Following study document distribution, the external site will submit a draft consent form to the MCC for review within one week prior to the planned local IRB submission. The MCC will submit the external site consent to the NCCC PI and CTO for review and approval, as needed. Upon MCC approval of the draft consent, the external site will

submit the protocol, consent form and other study documents to the local IRB. Any consent form revisions requested by the local IRB must be approved by MCC prior to final local IRB approval.

Evidence of local IRB approval and copies of approved consent forms must be submitted to the MCC prior to site activation. The MCC will submit external site IRB approval letters to ORRP and other authorities, as necessary.

5.1 Continuing Review

All participating sites must document annual IRB review of the protocol. Annual renewal approval must be minimally obtained within 365 days of the previous approval or before the defined protocol expiration. External sites must provide an IRB approval letter and copy of the approved informed consent form to the MCC. External site annual review approval memos will be included in the NCCC-CISO continuing review packet.

Failure to receive approval by the local IRB within the required timeline or submission of an incomplete or inaccurate consent (missing sections, inaccurate language, etc.) will result in site accrual suspension until approval is obtained. If an external participating site displays trends of failure to meet approval deadlines, the external participating site may be permanently closed to accrual.

5.2 Protocol Amendments

Any consent form revisions requested by the local IRB must be approved by MCC prior to submissions to the local IRB for review and approval.

External sites must submit the local IRB approval letter and IRB approved informed consent document to the MCC within 90 days of receipt of the amended protocol documents. External sites must also provide the signed Protocol Signature Page and Investigator's Brochure Signature Page, when applicable.

6 CENTRAL REGISTRATION

All participants in the multi-site trial are subject to central registration, which is used for tracking study accrual, checking eligibility, and monitoring adequate participation of women and minorities. Subject registration will be conducted through the coordinating center at the NCCC-CISO. External sites will identify eligible subjects and verify enrollment availability with the MCC prior to consenting patients. The external site is required to notify the MCC of a new signed informed consent within 48 business hours and note the basic consent information on the screening log. A copy of the consent will accompany the complete eligibility packet for verification. The MCC will enter the patient, demographic, and consent information in the applicable USC database. The MCC will assign a study patient sequence ID and communicate this to the external site.

The Coordinating Center Program Hours are 8 am to 4 pm, Monday through Friday, based on the PST zone. The MCC will be closed on official government holidays unless otherwise indicated.

The contact number for the MCC is 323-865-3122. A copy of the registration sheet is located in the Appendices.

External sites will verify eligibility prior to submitting documents to the MCC for central registration. External sites must submit registration requests to the MCC at least one full business day prior to the planned treatment start date. Registration will require the external site to submit to the MCC all of the following:

- A completed registration form with patient demographics:
 - Zip code
 - Payor Source
 - Age
 - Sex
 - Race
 - Ethnicity
 - Initials
 - Date of Birth (DOB)
- A completed Eligibility Checklist signed by the investigator
- A copy of the most recently IRB-approved, patient signed informed consent form
- All required screening tests, within the time parameters specified by the protocol study calendar
- All other de-identified source documents needed to verify all points of eligibility
- Any On-Study forms for registration specified by protocol

These documents must be securely emailed to the MCC staff. With advance notice documents will also be accepted faxed to 323-865-0457. The MCC will verify completeness of documents and confirm eligibility. The MCC will enter the registration information in the USC OnCore[®] database. The MCC will then fax or securely email the completed Registration Form with the assigned study sequence ID to the external site as confirmation of patient registration.

Each external site must maintain a log of all subjects who sign informed consents. The log must also document an explanation for exclusion due to screen failure. The MCC will provide sites with a Patient Tracking Log at the time of site activation. In the event of screen failure, external sites must submit the Screen Failure form to the MCC within one business day of determining screen failure.

Participating sites are required to retain, in a confidential manner, sufficient information on each subject so that the subject may be contacted should the need arise.

All documents, investigative reports, or information relating to the patient are strictly confidential. Any patient specific reports (i.e. Pathology reports, MRI reports, Operative reports, etc.) submitted to the CISO-MCC must have the patient's full name and social security number redacted (blacked out) and the assigned CISO-MCC patient ID number, protocol number, and site number written in. Patient initials only may be included or retained for cross verification of identification.

A registration verification letter will be emailed (preferred) or faxed to the registering site within one working day for patients registered to CISO-MCC multi-site trials. Treatment may not be initiated until the site receives this faxed or emailed verification.

7 STUDY RECORDS

7.1 Case Report Forms

The investigator is required to ensure completion of case report forms (CRFs) designed to record all observations and data pertinent to the investigation of each individual treated with the drug or employed as a control in the study. Standardized CRFs will be provided for recording all data from each subject. It is the responsibility of the external site investigator to ensure that these CRFs are properly completed and transmitted to the MCC in a timely manner.

The MCC will provide access and training for external sites to enter data directly into the applicable USC databases. Documentation of training will be maintained by the MCC.

Alternatively, on rare occasions paper CRFs may be utilized and will be created by the MCC and distributed to external sites prior to site activation.

External sites will transmit paper CRFs as clinical outcome data in the following manner:

- All information requested on the CRFs must be provided. Only the protocol specific subject ID number and/or subject initials must appear on all CRFs to ensure subject confidentiality.
- On the rare occasion paper CRFs are used they must be typewritten or printed legibly using black ballpoint pen to ensure legibility of photocopied pages.
- Corrections are to be made with a single line through the error, then initialed and dated.
- The investigator must sign the designated pages to attest that the CRF is accurate and complete.
- Signed and completed CRFs must be submitted to the MCC electronically or via fax within two weeks of the subject's visit or as specified in the protocol or contract. If entering data directly into the USC OnCore® database, data must be entered within two weeks of the subject's visit completion of each cycle.

If study forms are submitted with missing data, the data will be queried with a memo outlining the missing information required. If the forms received are completed with questionable information, the submitting institution will receive a query with a request for information.

If study forms are not submitted on schedule the participating institution will receive a "Missing and Deficient Report" from the CISO-MCC noting the missing data/forms and the due date. This report will be generated on a monthly basis by the CISO-MCC.

The MCC will issue data queries to the external site, as necessary. External sites must respond to queries within seven calendar days of receipt. If data is more than 30 days late a conference call will be placed by the CISO-MCC to the participating institutions, speaking to the senior operations

contact. If forms are 60 or more days late a phone call may be placed by the Protocol PI to the participating institution's Principal Investigator.

External site non-compliance with data submission schedules or submission of grossly or chronically inaccurate information may adversely affect the study and therefore may result in study suspension or closure to accrual for the site.

7.2 Source Documentation

All data recorded in the CRF must be traceable to the subject's source documentation. Source documents are the original records of subject information and contain all the information related to a subject's clinical protocol treatment. An investigator or their delegate is required to prepare and maintain adequate and accurate source documentation, to record all observations and verify the integrity of the study data, to confirm subject eligibility, and to assure that protocol procedures were followed. If an outside physician/institution other than the responsible study investigator treats a subject, it is the responsibility of the investigator or their delegate to obtain the medical records for those visits.

All subject source documents must adhere to the following standards:

- Subject's name, date of birth, or medical record number included on each page (except when transmitting source documents to the MCC, in which case subject identifiable information must be blacked out, and only initials and subject number should be included)
- Legibly written in ink, clearly typed or printed
- Signed and dated in a real time basis by the health care practitioner evaluating or treating the subject
- Corrections made with a single line through the error, and then initialed and dated.
- Diagnostic reports such as laboratory reports, pathology reports, x-rays, and scans must have complete laboratory-identifying information (name and address of the laboratory analyzing and reporting the results)
- Laboratory reports should indicate the range of normal values for each result listed, if applicable.

7.3 Regulatory Binder

The Regulatory Binder contains all approved versions of the protocol and consent forms, all IRB approvals and correspondence. It does not include completed subject CRFs or signed subject informed consent forms, which are maintained in the subject's research file. Typically, the binder contains the elements described in the Regulatory Binder Checklist (Appendix B). Each site is responsible for obtaining and maintaining their own Regulatory Binder.

7.4 Study Closure

Once the specified number of subjects for the study or site is registered, the study will be closed to accrual as determined by the NCCC PI. After the study closes to accrual, enrolled subjects will

continue to receive treatment and follow-up according to the protocol. The NCCC-CISO will officially terminate the study after the last subject reaches the maximum follow-up point and the results of all study data and specimens are analyzed and published, when applicable. The NCCC-CISO can close the study at any time if subject safety is compromised or if the protocol objectives are not being met in a reasonable time frame.

External sites may not independently close the NCCC protocol with their local IRBs, unless approval is requested and granted by the MCC.

7.5 Record Retention

The FDA requires the investigator to retain research records for a period of two years following the date a marketing application is approved for the indication being investigated. If no application is to be filed or the application is not approved for such indication, the records must be retained until two years after the investigation is discontinued and regulatory agencies are notified.

For investigator initiated non-IND studies, the principal investigator should retain research records a minimum of five years from the study's completion. If the study is published, records should be retained a minimum of two years from the first major publication.

8 DRUG ORDERING, ACCOUNTABILITY AND STORAGE

The record keeping described in this section is required under FDA regulation to ensure that study agents are used only for subjects entered onto an approved protocol. Investigators are responsible for the use of study agents shipped in their name. The investigator is ultimately responsible and has agreed to accept this responsibility by signing the FDA 1572.

Each external site is responsible for ordering their study drugs from the pharmaceutical company or its designee and such procedures should be detailed in the protocol. Similarly, each investigator is responsible for the proper and secure physical storage and record keeping of study agents. A drug accountability record form (DARF) must be used for documenting the disposition of all study agents. The use of an NCI DARF is recommended.

8.1 Storage of Study Drugs

Study agents must be stored in a secure location, accessible only by authorized personnel, preferably in the pharmacy.

Each study agent must be stored separately by protocol. If an agent is used for more than one protocol, there should be separate physical storage location for each protocol.

Sites must maintain appropriate storage of the study agent to ensure the stability and integrity of the agent. Refrigerated products should be stored between 2°C to 8°C (35°F to 46°F) and temperature readings from this storage location should be obtained at least once daily, or as indicated in the protocol, Investigator's Brochure (IB), or other relevant document.

8.2 Procedures for Study Drug Accountability

The management and accountability for study drugs in the multi-site trial is in keeping with the policies and procedures on the National Cancer Institute Cancer Therapy Evaluation Program website. All policies and guidelines may be found at https://ctep.cancer.gov/branches/pmb/agent_management.htm. The NCI DARF can be found at https://ctep.cancer.gov/forms/docs/agent_accountability.pdf and https://ctep.cancer.gov/forms/docs/oral_agent_accountability.pdf

The following policies have been established through the Pharmaceutical Management Branch and are endorsed by CISO-MCC:

- Each study drug must be accounted for separately, by protocol.
- If an agent is used for more than one protocol, there should be a separate DARF for each protocol.
- There must be a separate DARF for each agent in a multi-agent protocol.
- Separate accountability forms should be maintained for each different strength or dosage form of a particular study drug (e.g., a drug with a 1-mg vial and a 5-mg vial would require a different DARF for the 1-mg vial than for the 5-mg vial).
- The DARF must be designed for use at each location where study drugs are stored (e.g., main pharmacy, satellite pharmacy, physician's office, or other dispensing areas).
- The DARF must also be designed to accommodate both dispensing records and other study drug transaction documentation (e.g., receipt of agent, returns, broken vials, etc.).

8.3 Study Drug Destruction and Transfers

Sites must obtain approval from the MCC to destroy expired and/or unused study drugs. Each site is responsible for study drug accountability, which includes receipt, distribution, and final disposition of all study drugs. Transfer of study drug from one NCCC sponsored trial to another is acceptable only with written approval on file from the supplier of study drug and the MCC.

8.4 Verification of Compliance

Compliance with procedures to ensure proper study drug usage will be reviewed during the site qualification conducted by the MCC. External sites must ensure the agent accountability system is being maintained, that drug supply is sufficient for anticipated needs, drugs are properly stored, randomization labels (if applicable) are maintained. Drug accountability records may be compared to subject medical records to verify that the study drugs were administered to subject entered in the protocol of record. Copies of drug accountability records will be faxed or securely emailed to the MCC. All records are subject to request on demand within 5 calendar days.

8.5 Administering Study Drug

The external site investigator is responsible for the administration of all study drugs. A trained physician or chemotherapy nurse may administer investigational study drugs under the direct supervision of an investigator. It is the responsibility of each investigator to ensure that proper clinical observations and decisions are made to ensure subject safety and that the protocol is followed.

9 CENTRAL REPORTING OF ADVERSE EVENTS

An adverse event (AE) is an unfavorable or unintended sign, symptom or disease that may or may not be related to the study drug, procedure or treatment. All AEs must be entered into the subject's AE log.

Unless otherwise specified in the protocol, the study will utilize the Cancer Therapy Evaluation Program (CTEP) Common Toxicity Criteria (CTC) Version 4.0 for toxicity and adverse event reporting. A copy of the CTC or CTCAE Criteria can be downloaded from the CTEP home page (<http://ctep.info.nih.gov>).

Serious Adverse Event (SAE) is defined as any adverse drug experience occurring at any dose that results in any of the following outcomes:

- Life-threatening
- Death
- Hospitalization/prolongation of hospitalization \geq 24hrs.
- Congenital anomaly
- Persistent or significant disability/incapacity
- Any other medical event that, in the medical judgment of the investigator, may jeopardize the subject or may require medical or surgical intervention to prevent one of the outcomes listed above.

9.1 Significant Adverse Event (SAE) Reporting

The NCCC PI will be notified of all SAEs/UPs on multi-center clinical trials, with oversight from the USC Norris Data & Safety Monitoring Committee (DSMC). As the sponsor of the trial, this notification and documentation will be coordinated and maintained by USC through the CISO-MCC Coordinator. The SAE/UP reporting for multi-center clinical trials will follow the NCCC-CISO policies and guidelines as outlined in the Data Safety Monitoring Plan. Specific procedures for reporting an SAE to the MCC should be followed as detailed in each individual protocol. Of note:

- All SAEs must be reported to the CISO-MCC within 24 hours of occurrence or notification, unless otherwise noted in the protocol. The NCCC PI is considered the sponsor for IND-held or IND-exempt investigator initiated trials and is responsible for FDA and other reporting as detailed within the protocol. External sites are not permitted to report SAEs to the FDA.
- External sites are responsible for reporting SAEs to their IRB per institutional policy.

- All new SAEs will be reviewed during the mandatory study data and safety review teleconferences. SAE reports will be reported to external sites in real-time, if indicated for subject safety.

9.2 Suspected Unexpected Serious Adverse Reactions (SUSARs)

Unexpected serious adverse reactions which occur during the clinical trial or clinical care are adverse reactions that are not consistent with the product information. These are reported using the protocol specific mechanism (AERs, Medwatch, etc.) within 15 days when both serious and unexpected. Events which constitute a “serious” adverse reaction include:

- Death
- A life-threatening episode requiring immediate intervention
- An event resulting in hospitalization or that prolongs existing hospitalization
- Events resulting in persistent or significant incapacitation or disability
- A congenital anomaly or birth defect
- An episode that requires intervention to prevent the above and/r permanent impairment or damage

All SUSARs will be uploaded into the Medidata RAVE electronic data capture system (EDS) on a monthly basis for review and follow-up actions by the trial Principal Investigator. Study specific SUSARs will be reviewed at the time of study data and safety review teleconferences.

Guidelines for Processing IND Safety Reports

The U.S. Food and Drug Administration (FDA) regulations require sponsors of clinical studies conducted under a U.S. IND to notify the FDA and all participating investigators of any serious and unexpected adverse experiences that are possible related to the investigational agent. In compliance with these FDA regulations, CISO-MCC will notify the external investigators by the following methods:

IND Safety Reports: Investigators will be sent a copy of expedited adverse events which CISO-MCC has sent to the FDA. Within 7 business days of receipt of the notification, the CISO-MCC will forward the letters to the participating members with protocol specific instructions for IRB submissions, patient notifications, etc. For routine IND Safety Reports, CISO-MCC does not generally require an immediate revision to the protocol and/or model informed consent documents. The investigators are to file a copy with their protocol file and send a copy to their IRB according to their local IRB’s policies and procedures.

10 REPORTING PROTOCOL DEVIATIONS

Protocol deviation refers to any other unplanned instance of protocol noncompliance. For example: situations in which the investigator failed to perform tests or examinations as required by the protocol or failure of study participants to complete scheduled visits as required by the protocol. Neither the FDA nor the ICH GCP guidelines define the terms “protocol violation” or “protocol deviation”. The definition is often left to the Lead Institution IRB. Accordingly, since USC CISO-MCC

MCC is the lead organization and the USC PI must adhere to those policies set by the USC IRB, the definitions for protocol violation and deviation as described by the USC IRB will be applied for reporting purposes for all institutions participating in the CISO-MCC.

External sites must adhere to MCC and the local IRBs protocol deviation policy and report to the MCC all protocol deviations at least monthly via the Patient Tracking Log. Any deviations that may jeopardize subject safety or the research data must be reported to the MCC within 24 hours of occurrence or notification.

11 SAFETY REPORTS & PROTOCOL ALERTS

11.1 External IND Safety Reports

The NCCC PI will review all internal and external safety reports and provide direction on protocol and/or informed consent form amendments as a result of new safety information, when appropriate.

All external Sudden Unexpected Serious Adverse Reactions (SUSARs) will be made available to the external sites via the Electronic Data Capture (EDC) system in use on a quarterly basis. Sites are responsible for review and distribution/reporting based on their local IRB Guidelines. The information will have an accompanying Excel Spreadsheet which will be printed, signed by the site PI and returned as acknowledgement of SUSAR review.

11.2 Investigator's Brochures

The NCCC PI will review Investigator's Brochures (IBs) and supplement texts and provide direction on protocol and/or informed consent form amendments as a result of new safety information, when appropriate. The MCC will distribute IBs and supplement texts to external sites and provide direction for action as determined by the NCCC PI. External sites must review and submit all IBs and supplement texts to the local IRB as per local policy or as directed by the MCC and NCCC PI.

12 DATA SAFETY AND MONITORING

The NCCC Data and Safety Monitoring Committee (DSMC) will monitor all NCCC initiated multi-center studies. The NCI approved Data and Safety Monitoring Plan includes detailed monitoring procedures. See Appendix C for language to be included in all protocols.

Prior to site activation and opening to accrual, external participating sites on USC led multi-center trials are required to submit to the MCC team the site's local SOPs and other policy/procedure documents regarding local internal auditing and data & safety monitoring plans. If the external site does not have or is not able to provide local SOPs and policy/procedure documents, the NCCC CTO SOPs and applicable policy/procedure documents will be sent to the external site for local PI and clinical trials administrative review and sign off prior to site activation and opening to accrual.

If external sites have local policies and procedures that require them to perform internal auditing or data and safety monitoring of their patients enrolled to USC trials, the local auditing and/or

monitoring schedule must be provided to the MCC team and USC PI. In addition, auditing and/or monitoring reports must be provided to the MCC team and USC PI within 2 weeks of issuance of the local report to the external site study team or local PI. Remote auditing will be conducted yearly or more frequently as needed, regardless of the external site's monitoring policies. The USC Audit Team, may elect to do an independent review if major issues are found on the local reports. The first two patients registered on a protocol will be audited. USC will notify external site study teams via an email reminder of an upcoming audit at least 2 weeks prior to a scheduled audit.

Auditing will be performed on multi-site protocols opened by the CISO-MCC. All reviews will be performed remotely, unless otherwise specified in a contractual agreement and agreed upon by both institutions. The MCC and external site study team will make available the required medical records, research files, regulatory documents and other documentation via a secure electronic method agreed upon by both parties. The Clinical Research Auditor will review these materials during the audit or monitoring review. Once the review for each subject selected is complete, a final report will be made available. Trends and other important findings will be reviewed during the standing trial and safety review teleconferences organized by the MCC. Specific findings for individual external sites will not be outlined during all-site teleconferences, but will rather be provided to the respective site during a dedicated teleconference with the site or via email, depending on the findings.

The CISO-MCC may require a “for cause” audit; this audit is required when significant findings or data indicate potential issues on the part of the site. The USC PI of the trial reserves the right to call for this audit with all sites.

If the audit reveals compliance issues, further follow up will include:

- A re-audit of the protocol in question by the MCC
- Suspension of an external site or the entire protocol to accrual or conduct at the discretion of the USC DSMC
- Recommendation of permanent closure of the protocol to the IRB; this is a rare occurrence and has to be done in consultation with USC PI and CISO leadership.

The final USC DSMC determination will be sent in writing to the PI copying the study team within 48 hours of the DSMC meeting.

APPENDIX A: LIST OF SOURCE DOCUMENTS

Source documents may include but are not limited to the following items:

- De-identified institutional, research, clinic, or office subject records containing:
 - Inpatient and outpatient medical records
 - Progress notes
 - Consults
 - Physician notes
 - Nursing notes
 - Pathology reports
 - Radiology reports
 - Medicine/radiation administration records
 - Surgical reports
 - Laboratory results
 - Admission forms
 - Flow sheets that are signed and dated (signed flowsheets are considered source documentation only if data is recorded on them first – there must be no other source)
 - Tumor Measurement Flow Sheets
 - Protocol or study road maps
 - Appointment books
 - Subject diaries/calendars
 - Drug accountability forms
- Relevant subject-specific written communication from non-study health care providers, including comments related to past medical history, entry criteria, or other referral or follow-up information.
- Subject-specific correspondence, such as documented telephone calls, e-mail messages, and faxes.
- Obituaries, autopsy reports, and death certificates.

APPENDIX B: REGULATORY BINDER CHECKLIST

- ☐ Protocol and Amendments – all IRB approved versions
- ☐ Informed Consent and Amendments – all IRB approved versions
 - ☐ NOTE: Original signed subject informed consents are kept in the subject's medical or research records and not in the Regulatory Binder.
- ☐ IRB approval documents and correspondence
 - ☐ Protocol and amendment approvals including annual and periodic review approvals
 - ☐ Original informed consent form and amendment approvals
 - ☐ Other written (educational) materials provided to the subjects
 - ☐ Advertising for study recruitment
 - ☐ Notification of new safety information and the IRB's recommendations pertaining to this information
- ☐ Investigator Brochure if IND Study (all versions)
- ☐ Study Team Documents
 - ☐ Signed FDA 1572 Forms
 - ☐ Curriculum Vitae and documentation of professional licensure of all investigators and research team members where appropriate
 - ☐ Conflict of Interest Forms for research team members
- ☐ Logs
 - ☐ Signature Log (Site Personnel Signature Sheet)
 - ☐ Subject Identification List – This is a confidential list of the names of all subjects with their protocol assigned subject identification number. It is maintained only at the site and allows the investigator or institution to quickly identify study subjects in the case of an emergency.
 - ☐ Subject Screening Log

- ☐ Serious Adverse Event and IND Safety Reports
- ☐ Clinical Laboratory Certification (if required) and normal ranges
- ☐ Study Drug Documentation
 - ☐ Drug Shipment and Receipt Records/Forms
 - ☐ Accountability Logs
 - ☐ Drug Accountability Record Forms (DARFs)
 - ☐ NOTE: Study drug documentation may be kept, depending on the drug or agent and how it is dispensed, in the pharmacy binder and a copy in the Regulatory Binder.
- ☐ Other Study Correspondence
- ☐ Study Closeout Information

APPENDIX C: EXTERNAL PARTICIPATING SITE REGULATORY CHECKLIST

Study Information	
USC Study #	
Principal Investigator	
Protocol Title	
External Participating Site Information	
External Participating Site name	
Local Study #	

Regulatory Documents: All regulatory original (wet-ink) documents to be maintained by external site; copy to be sent to MCC.

- ☐ Signed & Dated FDA 1572
- ☐ Signed & Dated Financial Disclosure Form for each Investigator listed on 1572 (
- ☐ Delegation of Authority Log
- ☐ Protocol Signature Page
- ☐ Investigator Brochure Signature Page
- ☐ Drafted Informed Consent Document for review and approval by MCC prior to submission to local IRB of record
- ☐ Certificate of completion of Human Subjects Protection training for research staff members and investigators listed on the Delegation of Authority Log, scanned.
- ☐ Dangerous Goods shipping certification (ex: IATA Certificate of Completion) for each individual delegated authority to ship dangerous goods, scanned.

****Study specific regulatory documents will be dispensed to the site following pre-site activation.**

Investigator Qualification Documents

- ☐ Signed & Dated Curriculum Vitae for each Investigator listed on 1572
- ☐ Current Medical License for each Investigator on 1572
- ☐ Signed & Dated Curriculum Vitae for Laboratory Director
- ☐ Current Medical License for Laboratory Director

Local IRB Documents

- ☐ IRB Roster(s)
- ☐ OHRP Assurance Number
- ☐ FWA Number
- ☐ Institutional Review Board (IRB) Initial Approval Letter
- ☐ IRB Approved Informed Consent Form (ICF)
- ☐ IRB Approved HIPPA (if separate from ICF)

Policies & Procedures

- ☐ Investigational Product Disposal Policy
- ☐ Institutional Data & Safety Monitoring Plan/Policy
- ☐ List of Local SOPs

Laboratory Documents

- ☐ Laboratory Reference Ranges
- ☐ Laboratory CAP Certificate (US)
- ☐ Laboratory CLIA Certificate (US)

Contact Information

- ☐ External Participating Site Contact Sheet
- ☐ Pharmacy Contact Information (name, address, phone, fax, email)
- ☐ Clinicaltrials.gov Site Contact Sheet (NCCC-CISO MCC Manual Appendix H)

Date final electronic documents submitted to NCCC CISO-MCC: _____

Date required wet-ink documents mailed to NCCC CISO-MCC: _____

Name (Print): _____

Signature: _____ Date: _____

APPENDIX D: CLINICALTRIALS.GOV INFORMATION

Study Information	
USC Study #	
USC Principal Investigator	
Protocol Title	
External Site Facility Information for ClinicalTrials.gov Website	
External Site Facility Name	
City	
State	
Zip	
Country	
Local Study #	
Local Principal Investigator Name	
Name of person completing form	
Date form completed	
External Site Designated Contact for ClinicalTrials.gov Website	
First Name	
Last Name	
Degree(s)	
Phone Number	
Email Address	
External Site Designated Backup Contact for ClinicalTrials.gov Website (Optional)	
First Name	
Last Name	
Degree(s)	
Phone Number	
Email Address	

Appendix E

Site Teleconference Agenda

<DATE>

<Time>

Dial-in # /Web Ex Information

Attendees	Present	Attendees	Present

- Attendance
- Patient Status Overview- Enrollment Update
- PI/Site clinical review of study subjects
- USC clinical review of safety data
- Other Potential Subject Updates
- Other items for discussion: (floor open to topics)

Enrolled patients:

Cohort Slot #	Subject #	Age	Gender (M/F)	Cancer	Metastasis	Dose (total dose)	C1D1 Start	Evaluable ? (Y/N)	Comments
1									
2									

Prospective patients (in order C1D1 readiness)

Site	Subject #	Age	Gender (M/F)	Cancer	Metastasis	Dose Cohort	C1D1 Start	Comments

Complete/Closed Cohorts:

Cohort Slot #	Subject #	Age	Gender (M/F)	Cancer	Metastasis	Dose (total dose)	C1D1 Start	Evaluable ? (Y/N)	Comments

APPENDIX F

REGISTRATION REQUEST FORM

PROTOCOL NUMBER: _____

Patient Initials (First-Middle-Last):	
Address (zip Code):	Birth Date:
	Sex:
Race (Please check all that apply): <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Asian <input type="checkbox"/> Native Hawaiian or Pacific Islander <input type="checkbox"/> Other	
Ethnicity (Please check): <input type="checkbox"/> Hispanic <input type="checkbox"/> Non-Hispanic <input type="checkbox"/> Other	
U.S. Resident?: <input type="checkbox"/> Yes <input type="checkbox"/> No If No, enter Country of Residence:	
Method of Payment (Please check): <input type="checkbox"/> Private Insurance; <input type="checkbox"/> Medicare; <input type="checkbox"/> Medicare & Private Insurance; <input type="checkbox"/> Medicaid; <input type="checkbox"/> Medicaid & Medicare; <input type="checkbox"/> Military or Veterans Administration Sponsored; <input type="checkbox"/> Self Pay (No Insurance); <input type="checkbox"/> No Means of Payment (No Insurance); <input type="checkbox"/> Unknown	
Date IC Signed ____/____/____ Time ____ am/pm	Date HIPAA Signed ____/____/____
Date of Request Form Submitted:	Site Name:
Site Telephone #:	Site Principal Investigator Name:

By signing below, the Investigator attests to the review of the source documents for the protocol eligibility requirements.

 Eligibility reviewed by: Investigator Name

 Investigator Signature

 Date

Utilize the signed form as the cover sheet for the de-identified source doc submission when requesting MCC eligibility verification and registration

Appendix G

Site Qualification Form

Your site has shown interest to participate in a multi-site investigator initiated clinical trial described below. Please complete this form to be determined whether the study is feasible at your site:

Study Title:	<<USC staff to complete>>
Study Chair:	<<USC staff to complete>>

Site Name:	
Site Address:	

SITE CONTACT INFORMATION	
PRINCIPAL INVESTIGATOR	
Name	
Telephone	
E-mail	
Address (if different from the site address)	
REGULATORY CONTACT	
Name	
Telephone	
E-mail	
Address (if different from the site address)	
RESEARCH PHARMACY	
Pharmacist Name	
Telephone	

E-mail		
Address (if different from the site address)		
BUDGET and CONTRACT		
Name		
Telephone		
E-mail		
Address (if different from the site address)		
OTHER RELEVANT CONTACTS		
Name		
E-mail		
Role		
Name		
E-mail		
Role		

SITE SPECIFIC INFORMATION
<p>Based on the protocol are all of the study requirements feasible at your site?</p> <p>Will this study be conducted at a single site? <i>(please circle one)</i> YES or NO</p> <p><i>If No- Please list all affiliated sites and contact information</i></p>

SUBJECT RECRUITMENT
Based on the protocol how many subjects are anticipated to be screened monthly?
Based on the protocol how many subjects are anticipated to be enrolled monthly?
How many competing protocols are currently open?

ETHICS COMMITTEE
Does the site use local or central IRB?
How often does your IRB/IEC meet?
How many days must study documents be submitted before an IRB/IEC meeting?
What is the estimated time for an IRB/IEC approval?
Does the IRB/IEC require a fully executed contract prior to reviewing the study documents?
Will this study require approval from any other regulatory, scientific or ethics committee at your site? (please circle one) YES or NO
<i>If Yes- please specify the committee and if the reviews are conducted in parallel to the IRB review.</i>

PHARMACY
Is a pharmacist at your site specifically appointed for the management of clinical trials, including appropriate drug dispensing and accountability procedures?
Where will the study drug(s) be stored before being dispensed?

Is the following pharmacy equipment available at your site?:	
+4 degree freezer	(please circle one) YES or NO
-20 degree freezer	(please circle one) YES or NO
-80 degree freezer	(please circle one) YES or NO

LABORATORY EQUIPMENT	
Centrifuge for spinning blood samples available?	(please circle one) YES or NO
Refrigerated centrifuge for spinning blood samples available?	(please circle one) YES or NO

<p>_____</p> <p>Name of the site personnel completing this form</p>	
<p>_____</p> <p>Signature</p>	<p>_____</p> <p>Date</p>