Purpose:
This standard operating procedure (SOP) defines the responsibilities of the clinical research team for conducting clinical studies at the University of Arizona Cancer Center. It identifies administrative accountability as well as general responsibilities of the clinical research team and of individual team members for fulfilling regulatory and clinical requirements.

References:
- 21 CFR 312.53 Selecting investigators and monitors.
- 21 CFR 312.60 General responsibilities of investigators.
- 21 CFR 312.61 Control of the investigational drug.
- 21 CFR 312.62 Investigator record keeping and record retention.
- 21 CFR 312.64 Investigator reports.
- 21 CFR 312.66 Assurance of IRB reviews.
- 21 CFR 312.68 Inspection of investigator's records and reports.
- 21 CFR 312.69 Handling of controlled substances.
- 21 CFR 54 Financial Disclosure by Clinical Investigators.
- May 1997 International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline.
- Standard Operating Procedures for Good Clinical Practice at the Investigative Site by A. Shefrin, C. Saunders.
- ICH GCP 5.18 Monitoring.
- ICH GCP 5.19 Audit.
- All SOPs are applicable to this SOP.

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
This SOP applies to those members of the clinical research team involved in developing, implementing, managing and overseeing clinical trials conducted at UACC. This includes the following:

- Principal Investigator (PI)
- Co-Principal Investigator (Co-PI)
- Sub-Investigator
- Clinical Trials Office (CTO)
- IRB Coordinator
- Regulatory Specialist
- Research Nurse Coordinator
- Clinical Research Coordinator (CRC)
- Investigational Pharmacist
- Clinical Research Assistant
- SRC (Scientific Review Committee)
- IRB (Institutional Review Board)
- WIRB (Western Institutional Review Board)
- IBC (Institutional Biosafety Committee)
- RSC (Radiation Safety Committee)
- Support Staff
- Clinical Research Shared Service Teams (comprised of a group of research nurse coordinators, clinical research coordinators (CRCs), IRB coordinators, regulatory specialist and administrative support staff)
- Contracts and Grants Administrator
- QA/QC Program Monitor
- QA/QC Program Auditor

Tools:
- Form FDA 1572
- Delegation of Responsibility (Tasks) Form (Attachment 1)
- Principal Investigator Responsibilities Description (Attachment 2)
- Research Nurse Coordinator Responsibilities Description (Attachment 3)
- Clinical Research Coordinator Responsibilities Description (Attachment 4)
- Clinical Research Assistant Responsibilities Description (Attachment 5)
- Clinical Support Staff Responsibilities Description (Attachment 6)
- IRB Coordinator Responsibilities (Attachment 7)
- Regulatory Specialist Responsibilities (Attachment 8)
- Clinical Trials Office Responsibilities Description (Attachment 9)
- Investigational Pharmacist Responsibilities Description (SOP 201 PHM)
- Contracts and Grants Administrator
- QA/QC Program Monitor (Attachment 10)
- QA/QC Program Auditor (Attachment 11)
Definition of Terms:

- **Auditor**: Person responsible for systematic examination of trial activities and documents to determine whether the evaluated trial activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, CRSS Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

- **Clinical Cancer Research Conference (CCRC)**: Multidisciplinary bi-monthly meetings held to present Phase I studies (which include new agents for development); to review ongoing clinical trials and to announce new potential studies for drug development.

- **Clinical trial/study**: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms “clinical trial” and “clinical study” are synonymous.

- **Co-Principal Investigator (Co-PI)**: Assists the PI with the conduct of the clinical study. He or she oversees all aspects from IRB submissions to patient care. Signs as the principal investigator and/or presenter on the informed consent document.

- **Institutional Review Board (IRB) or Western Institutional Review Board (WIRB)**: An independent body constituted of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well being of human subjects involved in a trial by, among other things, reviewing, approving and providing continuing review of trial protocol and amendments and of the methods and materials to be used in obtaining and documenting informed consent of the trial subjects.

- **Monitor**: Person employed by the sponsor or CRO who is responsible for determining that a trial is being conducted in accordance with the protocol. A monitor’s duties may include, but are not limited to, helping to plan and initiate a trial, assessing the conduct of trials, and assisting in data analysis, interpretation, and extrapolation. Monitors work with the clinical research coordinator to check all data and documentation from the trial.

- **OnCore**: Database used to store protocol and patient data at the University of Arizona Cancer Center.

- **Principal Investigator (PI)**: The individual who is ultimately responsible for the conduct of the clinical trial. He or she oversees all aspects from IRB submissions to patient care. Signs as the investigator and/or the presenter on the informed consent document.

- **Sub-Investigator**: Any individual member of the clinical trial team designated and supervised by the investigator (or Principal Investigator) at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, nurse practitioners) and are included on the Form FDA 1572. Can sign as a presenter only on the informed consent document.
Process Steps:

A. Administrative responsibilities

Director Clinical Research Shared Service and/or Associate Director Clinical Trials and/or Clinical Research Nurse Manager and/or Manager Clinical Trials Office, Contracts and Grants Administrator

Participate as appropriate in the hiring and training of individuals recruited as members of the research team.

Assign, in conjunction with the designated clinical research team leaders, trained research nurse coordinators and clinical research coordinators to manage each clinical study planned or ongoing associated with the respective clinical research team and principal investigators.

Manage the business aspects of studies, including developing and negotiating study budgets and contracts.

Ensure that there are adequate numbers of qualified staff members to conduct the study and that there are adequate facilities in which to conduct the study.

Oversee the management, development and implementation of OnCore.

Communicate with the UACC administration, SRC, IRB and WIRB as appropriate.

B. General responsibilities of the research team

PI, Co-PI, Sub-Investigator, Clinical Research Coordinator, Research Nurse Coordinator, Clinical Research Assistant, Investigational Pharmacist, Support Staff, IRB Coordinator, Regulatory Specialist

Conduct clinical studies according to FDA regulations, GCP and ICH guidelines, SOPs and policies and procedures at UACC.

Principal Investigator is informed, in a timely manner, of all study-related activities through weekly team meetings, memos, reports and email.

Ensure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and investigational products.

All investigators and research personnel must comply with local, state and federal regulations governing disclosure of personal, professional or financial interests in a research study that may affect its conduct, evaluation or outcome.

C. Individual responsibilities within the research team

- Principal Investigator (Attachment 2)

Sign Form FDA 1572 to acknowledge responsibilities as defined by the regulations (Form FDA 1572, http://www.fda.gov/opacom/morechoices/fdaforms/cder.html).

Provide sponsor with required information that:
Attest to the absence of financial interests or arrangements as described in the regulations (CFR 54.4) and reported on Form FDA 3454 that is completed by the sponsor, or provides the sponsor a complete and accurate disclosure of financial interests and arrangements as described in the regulations (CFR 54.4) and reported on Form FDA 3455 that is completed by the sponsor.

While retaining knowledge of and overall authority for the conduct of all studies, supervise members of the research team qualified by their education and training to accept these responsibilities for study-related activities not directly performed by the PI.

Document the delegation of responsibilities (tasks) (Attachment 1, Delegation of Responsibility Form).

Ensure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and investigational articles.

Participate as appropriate in the hiring and training of individuals recruited as members of the research team.

Ensure that specific sponsor requirements of the PI are fulfilled as requested. Meet with sponsors’ representatives as appropriate to discuss planned and ongoing studies.

Meet with auditors (internal, sponsor and FDA) at the conclusion of their audits to review findings.

- Research Nurse Coordinator and/or Clinical Research Coordinator (Attachments 3 and 4)
  Develop organizational aids and checklists to facilitate patient recruitment and enrollment as well as the collection of complete and accurate study data.
  Enroll subjects in studies and manage their participation according to ethical, regulatory, and protocol-specific requirements.

Track study enrollment.

Maintain study files for each research project and ensure secure storage of medical records.

Maintain confidentiality of study subject’s identity.

Participate in quality assurance activities (monitoring visits, internal audits, sponsor audits, FDA audits).

- Clinical Research Assistant (Attachment 5)
  Develop and organize pharmacokinetic studies for all clinical trials with support from the research nurse coordinator.

Process, store and ship study related samples.
Support Staff (Attachment 6)

Communicate with the financial office in regard to insurance authorizations, study start and end dates.

Coordinate the scheduling of study-specific screening tests and procedures.

Schedule research subjects on-study appointments with guidance from research nurse coordinator, clinical research coordinator and principal investigator.

Photocopy, update clinic research packets, file informed consent documents, obtain records, ship specimens and inventory control of supplies.
- **IRB Coordinator (Attachment 7)**
  Initiate communications between Study Sponsor and Investigator; obtain study documents from sponsor.

  Prepare study information and route documents for Study Team review and approval, and Budget and contract review.

  Prepare documents for submission and approval by Scientific Review Committee (SRC), Institutional Review Board (IRB) and/or Western Institutional Review Board (WIRB), Institutional Biosafety Committee (IBC); DSMB (Data Safety Monitoring Board), Radiation Safety Committee; Red Cross and any other oversight committees as may be required per study.

  Maintain and prepare all study protocol changes, consent changes, safety reports (LSAEs and industry safety reports), and annual review reports for submission and approval.

  Enter new study protocols, and all submissions and approvals into OnCore; notify and supply study team with all protocol changes and approvals.

  Participate in Site Initiation Visits and study training procedures.

  Participate in quality assurance activities (monitoring visits, internal audits, sponsor audits, FDA audits).

  Provide written information of premature termination or suspension of a trial.

  Assist with sponsor close-out procedures and conclude the study with all oversight committees, the sponsor, and in OnCore.

  **IRB Coordinators-Senior:** (along with above)
  Update and assist in the training with fellow Clinical research shared services personnel of the clinical research database relating to study status, reviews, attachments, checklists and actions.

  Assist in the development of new standard operating procedures as needed for ethical/regulatory/privacy matters.

  Assist in the development of employee training manuals as well as training junior IRB coordinators and fellow clinical trials office staff.

  Assist disease team in developing strategies to ensure increased study awareness, subject enrollment, protocol compliance, including maintenance of protocol information tools for assigned disease team.
Develop presentations or posters for training of the Clinical Research Shared Service staff/personnel on the administrative workings of the clinical trials office.

- **Regulatory Specialist (Attachment 8)**
  Prepare all regulatory documentation: CVs and Licenses for all Investigators or Sub-Investigators; Form FDA 1572; Financial Disclosure Forms (FDFs); IRB certification and listing of all members CLIA and other certification for each laboratory used; Normal test values for all tests done at each Lab listed; Delegation of Duty and Site training logs required by the sponsor required prior to opening a new study and IRB roster.

Obtain required signatures from staff for all required regulatory documents and study logs.

Maintain and update all UACC personnel CITI training, CVs and licenses documentation in OnCore and on each study as staff changes occur.

Maintain a constant dialog with the study representatives to maintain and update regulatory documentation throughout the study, as required by the sponsor and/or regulatory agents.

Participate in quality assurance activities (monitoring visits, internal audits, sponsor audits, FDA audits).

Assist with the study close-out procedures with all oversight committees and the sponsor and in OnCore.

- **Clinical Trials Office (CTO) (Attachment 9)**
  Provide centralized protocol submission and management of all clinical trials conducted at the University of Arizona Cancer Center.

  Assist the research team in developing, implementing and managing the conduct of clinical trials and maintenance of regulatory documentation compliance.

  Submit documents to University of Arizona and UACC oversight committees, including SRC (Scientific Review Committee), Institutional Review Board (IRB) and/or Western Institutional Review Board (WIRB), Institutional Biosafety Committee (IBC), DSMB (Data and Safety Monitoring Board).

  Review submitted clinical trial documents to ensure that all appropriate components are present including study protocol, investigational drug brochure, informed consent form, and project approval form prior to distribution for resource or institutional committee review as appropriate.

  Maintain the regulatory documentation and regulatory files for each research project. Oversee the development and implementation of OnCore.
- **Clinical Research Team**
  Fulfill those job responsibilities following federal regulations, ICH and Good Clinical Practices guidelines as well as the appropriate SOPs.

  Team members will facilitate the change process: develop team goals and strategies to achieve goals, implement plans and evaluate outcomes.

  The clinical research team will facilitate and participate in the problem-solving process: identify problems, formulate alternative solutions, and implement solutions and evaluate outcomes.

  Work as a team in making effective decisions based on knowledge of administrative and clinical policies and procedures.

  Promote collaboration; provide support and backup to team members.

  Promote, develop and participate in training and educational activities such as investigator meetings, site evaluation visits, site initiation visits, Cancer Center presentations and scientific meetings.

- **QA/QC Program Monitor and Auditor (Attachments 10 and 11)**
  The QA/QC Program Monitor is responsible for monitoring activities for clinical trials as a continuous review of the conduct of the trial, including adherence to study design and documentation of appropriate reporting of related toxicities and adverse events. The monitor ensures that the trial is conducted and documented properly by carrying out the following activities that are relevant and necessary to the trial and the trial site.

  The QA/QC Program Auditor is responsible for evaluating trial conduct and compliance with the protocol, SOPs, GCP and applicable regulatory requirements.

  Both the QA/QC Program Monitor and Auditor fulfill their job responsibilities by following federal regulations, ICH and Good Clinical Practices guidelines as well as the appropriate SOPs.

  Both the QA/QC Program Monitor and Auditor facilitate the change process, develop team goals and strategies to achieve goals, implement plans and evaluate outcomes.

  Both the QA/QC Program Monitor and Auditor promote, develop and participate in training and educational activities such as Cancer Center presentations and scientific meetings.
### DELEGATION OF RESPONSIBILITIES

**Protocol Title:**  
**Protocol #:**  
**Principal Investigator Name:**

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<th>Signature</th>
<th>Initials</th>
<th>Role</th>
<th>Participation Start date</th>
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1. Informed Consent  
2. Subject Screening  
3. Protocol Related Procedures  
4. Medication Dispensing  
5. Drug Accountability  
6. Case Report Forms  
7. Query Resolution  
8. Process Lab Samples/PK Samples  
9. Maintain Regulatory Documents  
10. HIPAA Incident Reporting  
11. Other (specify)

I hereby delegate to each individual noted the responsibility to perform the task(s) indicated. I have determined that each individual is qualified and capable of performing the delegated task(s) indicated based on education, training or experience.

______________________________  _______________________________  ________________  
Signature of Principal Investigator  Printed Name  Date

Page _____ of _____
Attachment 2

Responsibilities: Principal Investigator
Promotes good clinical practices in the conduct of clinical investigations by assuring adherence to protocol requirements, protecting the rights and welfare of subjects, assuring the integrity of data generated at the site and directing the conduct of the clinical investigation according to federal and state regulations and guidance documents.

A. Provides investigator qualifications and agreements by:
   - assuming responsibility for the conduct of the clinical investigation;
   - maintaining a current, up-to-date curriculum vitae;
   - maintaining current licensure to practice;
   - providing the sponsor and IRB with documentation of credentials as requested;
   - demonstrating the proper education, training and experience to conduct the clinical investigation;
   - signing the Form FDA 1572 as appropriate;
   - signing the protocol as required;
   - signing sponsor contract(s) as appropriate;
   - disclosing conflicts of interest as described in the regulations.

B. Complies with the protocol by:
   - possessing a thorough understanding of the requirements of each protocol;
   - determining that inclusion/exclusion criteria are applicable to the study population;
   - assuring recruitment goals are reasonable and attainable;
   - assessing overall protocol feasibility;
   - following the trial’s randomization and registration procedures;
   - not implementing any protocol deviation or changes without agreement by the sponsor and prior review and approval by the IRB (except to eliminate immediate hazards to the subject);
   - reviewing the inclusion/exclusion criteria, schedule of visits, end point criteria and investigational article use with the research team;
   - reporting serious adverse events, toxicities to the IRB, FDA and study sponsor as appropriate.

C. Obtains initial and ongoing review (SRC, IRB, IBC) by:
   - working with the IRB Coordinator to provide the IRB with adequate information to initially review the study (i.e., Project Approval Form, protocol, investigator’s brochure, informed consent form, recruitment advertisements and any written information to be given to subject(s));
   - working with the IRB Coordinator to provide the IRB with documents for ongoing review (i.e., amendments to the protocol, serious adverse events, deaths, protocol deviations or new information);
working with the IRB Coordinator to report serious adverse events or death which must be reported to the UACC local IRB/WIRB within 10 working days of knowledge of the event (or as specified by the study protocol);

working with the IRB Coordinator to secure written IRB/WIRB approval prior to initiating the study or instituting any changes to the protocol as approved;

reviewing the IRB Coordinator’s written summaries of the trial status to the IRB/WIRB annually, or as requested;

providing written information of premature termination or suspension of a trial;

reviewing all IRB Coordinator prepared documents requiring IRB review and/or approval.

D. Manages the medical care of subjects by:

- assessing and documenting subject’s response to therapy;
- evaluating for adverse experiences;
- ensuring that medical care is provided to a subject for any adverse event(s), as appropriate;
- serving as a consultant in all study-related medical decisions (e.g., dose reductions, dose delays).

E. Protects the rights and welfare of subjects by:

- reporting all serious adverse events immediately to the sponsor and IRB/WIRB;
- assuring that the informed consent form contains all the elements required by CFR 56 and 45;
- obtaining a signed and dated informed consent form from the subject or subject’s legal representative prior to initiating any study-related procedures;
- ensuring that the current version of the informed consent was used;
- informing the subject or legal representative about all aspects of the clinical trial;
- providing new information about the study or test article(s) that may be developed or discovered during the course of the clinical trial that may affect a subject’s willingness to participate;
- ensuring subject confidentiality;
- providing the subject or subject’s legal representative with a copy of the signed and dated informed consent form;
- assuring that the informed consent form is in language that is understandable to the subject;
- securing a witness to the informed consent process when the subject or legal representative is unable to read;
- allowing ample time and opportunity for the consent process and answering questions about the trial to the satisfaction of the subject or legal representative;
- securing consent/assent from minors and mentally impaired subjects as appropriate;
- following emergency use guidelines for waiver of consent in emergency situations as directed by the federal regulations and IRB policy and procedures.
F. Validates the accuracy of data by:
   • ensuring the accuracy, completeness, legibility and timeliness of case report forms;
   • ensuring that case report forms accurately reflect source documents;
   • explaining any discrepancies between source documents and case report forms;
   • endorsing changes or corrections to a case report form.

G. Documents study-related procedures, processes and events by:
   • documenting deviations from the approved protocol and reporting deviations to the IRB and study sponsor;
   • documenting and explaining premature un-blinding of the investigational product(s);
   • documenting that informed consent has been obtained from the subject or legal representative prior to performing any study-related procedures;
   • documenting the reason for a patient's premature study withdrawal;
   • documenting adverse events;
   • complying with written procedures to document changes to data and/or case report forms;
   • providing study reports as requested by the sponsor, IRB and regulatory authorities.

H. Verifies the proper use and storage of investigational agents by:
   • being thoroughly familiar with the use of the investigational product(s);
   • reading the current investigator's brochure, product insert or other source information and updating the informed consent form as appropriate;
   • assuming responsibility for the investigational product at the trial site;
   • ensuring the proper use and storage of the investigational product(s) at the trial site;
   • reviewing the proper use of the study article(s) by the subject(s).

I. Directs site operations by:
   • communicating effectively with subjects, research team, IRB and sponsor;
   • meeting regularly with the research team to discuss subject participation and protocol progress;
   • assuring that all research staff are informed about the protocol and investigational agents;
   • being knowledgeable about regulatory requirements and GCP standards;
   • preparing for and attending investigator and start-up meetings;
   • participating in monitoring visits and audits as appropriate;
   • permitting monitoring and auditing by the sponsor and appropriate regulatory authorities;
   • making available to monitors, auditors, IRB and regulatory authorities all requested trial-related records;
   • delegating authority at the site appropriately;
   • assuring that all research staff are informed about their trial-related duties and functions;
   • maintaining a list of qualified persons and their corresponding trial-related delegated duties.
J. Maintains professional and technical knowledge by:
   • attending educational workshops;
   • reviewing professional publications;
   • participating in professional societies.
Responsibilities: Research Nurse Coordinator
The primary responsibility of the research nurse coordinator is to oversee and manage the conduct of clinical trials in a team based environment. The research nurse coordinator is required to have an in-depth knowledge of protocol requirements and good clinical practices as set forth by federal regulations. As the primary resource for the protocols, the research nurse coordinator will act as liaison between the investigators, primary care providers and the sponsor. Along with the investigator, the research nurse coordinator will review screening, treat and follow study subjects, ensuring protocol compliance and the close monitoring of subjects while on study. In addition, the research nurse coordinator is responsible for all data and source documentation, adverse event reporting and, as appropriate, administering therapy.

A. Sound conduct of the clinical trial, including but not limited to recruitment, screening, treatment and follow-up of eligible subjects according to protocol requirements (e.g., subject follow-up, providing and reviewing data for case report form completion and reporting of adverse events).
B. Maintenance of accurate and complete documentation, including but not limited to, signed informed consent forms, source documentation, subject logs, and study-related communications.
C. Organizational management of all aspects of the trial, including but not limited to overseeing timeliness in completing case report forms (CRFs) by data entry, reporting serious adverse events (SAEs), managing caseload and managing study files.
D. Communication of all protocol-related issues/problems to the appropriate team members, including but not limited to questions regarding the conduct of the clinical trial, concerns regarding possible SAE/AEs or subject compliance.
E. Professional conduct in the presence of subjects, research staff, sponsors and monitors, etc.
F. Maintain current professional licenses and certifications.

Specific responsibilities include, but are not limited to, the following:
A. Develop enrollment/follow-up mechanisms along with the clinical research coordinator;
   • possess a sound and in-depth understanding of each protocol that has been assigned as a primary responsibility;
   • participate in study site evaluation and site initiation meetings and provide training and support to other assigned study personnel;
   • review with the principal investigator and clinical research coordinator the inclusion/exclusion criteria, overall structure and requirements of each protocol;
   • may review IRB applications and ongoing amendments as requested.
B. Enrollment and follow-up of study subjects
   1. Screening and enrollment procedures:
SOP 107-ADM Responsibilities of the Clinical Research Team

1. Protocol, study design, informed consent form and follow-up procedures:
   - review the protocol, study design, informed consent form and follow-up procedures with potential study subjects;
   - ensure the current approved informed consent is signed before subjects are screened and enrolled;
   - ensure that the randomization procedure is followed as per protocol guidelines;
   - document protocol exemptions and deviations as appropriate.

2. Subject treatment and follow-up procedures:
   - ensure adherence to protocol requirements;
   - assess subject compliance with the investigational agent and report to PI any noncompliance and follow-up visits;
   - schedule subjects for follow-up visits;
   - assess and monitor subject response to therapy and interventions
   - evaluate and document adverse events and concomitant medications;
   - review laboratory data and communicate abnormal values to the primary care provider and investigator;
   - assess and document subject compliance with medications and visits;
   - communicate with pharmacy staff to assure timely and accurate study drug distribution;
   - review written orders prior to treatment and administer study drug therapy as needed;
   - maintain copies of all prescriptions written for study drug supplies as appropriate;
   - ensure appropriate specimen collection;
   - attend study-related meetings as appropriate;
   - communicate regularly with the principal investigator about study-related issues.

3. Case report form (CRF) preparation and study documentation:
   - ensure timely and accurate AE and Con Med CRF completion for each study subject;
   - key data for remote data entry or provide completed CRFs on a timely basis to clinical research coordinators;
   - review keyed data for accuracy as needed;
   - maintain source documentation for all CRF entries, including clinic chart visit notes, lab data and procedure reports;
   - correct and edit CRFs as appropriate.

4. Adverse event monitoring and reporting responsibilities:
   - assess and record all AEs as outlined in the protocol including OnCore data entry;
   - report all serious AEs to the principal investigator, sponsor, clinical research coordinator and IRB/WIRB as outlined in the protocol.

5. Sponsor and/or FDA audits:
   - ensure that all required clinical documentation is complete and appropriately filed;
   - provide all required clinical documentation to auditors;
6. Study closeout:
   • ensure that all study documentation (e.g., regulatory, IRB/WIRB communications, patient and drug logs, etc.) is appropriately filed.
Responsibilities: Clinical Research Coordinator
The primary responsibility of the clinical research coordinator is to screen and enroll subjects to clinical trials, enter data on case report forms (CRFs), and/or key data using remote data entry. The clinical research coordinator is responsible for collecting all source documentation and worksheets prepared by all members of the research team. She/he is responsible for gathering all outside source documentation and transcribing the data using the appropriate collection tool for submission to the sponsor.

A. Completeness and accuracy in performing assigned work, including but not limited to recording clinical data, both computer entry or data transcription.
B. Organization in performing assigned work, including but not limited to timeliness in completing projects, neatness of work performed and success in managing multiple tasks.
C. Professional conduct in the presence of subjects, research staff, sponsors, monitors, etc.

Specific responsibilities include, but are not limited to, the following:
A. Enrollment and follow-up of study subjects:
   1. Screening and enrollment procedures:
      • develop organizational aids and checklists to facilitate subject recruitment and enrollment as well as the collection of complete and accurate study data;
      • obtain, collect, review and verify all relevant source documentation in the subject's medical record to confirm study eligibility;
      • ensure the current approved informed consent is signed before subjects are screened and enrolled;
      • ensure that the randomization and registration procedures are followed as per protocol guidelines;
      • ensure completion of verification of subject eligibility form;
      • document protocol exemptions and deviations, as appropriate;
      • file and pull study-related records;
      • retrieve and review medical records;
      • transcribe and complete case report forms following ALCOA standard (attributable, legible, contemporaneous, original, accurate);
      • review data for accuracy and completeness;
      • clarify data with research staff as necessary;
      • assure proper storage of study subject’s medical records;
      • enter data into OnCore database;
      • correct, revise and document or track changes to data;
      • maintain electronic data in appropriate files (i.e., team folders, U-drive);
      • proper destruction of study documents containing patient identifier information, (i.e., subject listings).
2. Sponsor and/or FDA audits:
   • maintain clinical trial documents as required by the regulations and sponsor(s) for the appropriate timeframe and under secure conditions;
   • ensure that all required clinical documentation is complete and appropriately filed;
   • provide monitors or auditors with completed CRFs, medical records, lab data and other source documents for review;
   • make all appropriate corrections as requested by monitors or auditors.
3. Study closeout:
   • ensure that all clinical study documentation (e.g., communications, patient and drug logs, etc.) is appropriately and securely filed;
   • ensure that all CRFs are complete and that all forms have been forwarded to the sponsor or entered into OnCore as appropriate.
4. Prepare and store all research files in a designated, permanent and safe location.
Responsibilities: Clinical Research Assistant

The primary responsibility of the Clinical Research Assistant is to assist the research nurse coordinator and/or clinical research coordinator in conducting clinical trials. The clinical research assistant is responsible for collecting, processing, storing and handling clinical specimens, collecting and recording information for pharmacokinetic studies and acting as back up for scheduling study subjects.

A. Completeness and accuracy in performing assigned work, including but not limited to recording clinical data, sample collection and processing.
B. Communication of all protocol-related questions or problems to the research nurse coordinator or clinical research coordinator.
C. Professional conduct in the presence of subjects, research staff, sponsors, monitors, etc.

Specific responsibilities include, but are not limited to, the following:
- case report form documentation;
- phlebotomy;
- specimen collection, processing, storage, and shipment;
- follow Good Laboratory Practices and University of Arizona policies and procedures for biosafety precautions and blood borne pathogens;
- maintain equipment records;
- communicate with other study personnel (e.g., study monitors, central labs, etc.);
- source document collection as appropriate;
- filing and pulling study records as appropriate;
- transporting clinical specimens to the laboratory;
- appointment scheduling (backup).
Attachment 6

Responsibilities: Clinical Support Staff
The primary responsibility of the clinical support staff is to assist the research nurse coordinator, clinical research coordinator, and clinical research assistant in conducting clinical trials. The support staff is responsible for collecting, processing, storing, filing and handling study documents.

A. Completeness and accuracy in performing assigned work, including but not limited to recording of clinical data, sample collection and processing.
B. Communication of all protocol-related questions or problems to the research nurse coordinator or clinical research coordinator.
C. Professional conduct in the presence of subjects, research staff, sponsors, monitors, etc.

Specific responsibilities include, but are not limited to, the following:
- communicate with the financial office in regard to insurance authorizations, study start and end dates;
- coordinate the scheduling of study-specific screening tests and procedures;
- schedule research subject’s appointments with guidance from research nurse coordinator, clinical research coordinator and principal investigator;
- provide clerical support for photocopying, updating clinic research packets, filing of informed consent documents, obtaining records, shipping specimens, ordering and inventory control of supplies and answering and triage of research office calls.
Responsibilities: IRB Coordinator
The IRB Coordinator is the liaison for the preparation and submission of all study documents to the University of Arizona, UACC oversight committees, including the SRC (Scientific Review Committee), IRB (Institutional Review Board) and/or WIRB (Western Institutional Review Board), IBC (Institutional Biosafety Board), RSF (Radiation Safety Committee), DSMB (Data Safety Monitoring Board), and sponsors of the study.

A. The IRB Coordinator is responsible for assisting the Principal Investigator with initiating all new study review procedures and submissions for study approvals at the UACC.
   New study review:
   - Initial sponsor contact, procure protocol documents;
   - Obtain PI decision to proceed;
   - Route documents to study team, and budget and contract office;
   - Prepare Protocol Submission Form for team review;
   - Obtain written approval from team leader;
   - Obtain approval to proceed from budget and contract office.

B. Prepares all study documents for the approval processes.
   - Prepare Project Approval Forms (for Local IRB and WIRB); Consents (Informed Consent, HIPAA, Ancillary Consents as needed per study)
   - Obtain sponsor approval for consents (required prior to IRB submission);
   - Obtain IDB (Inter-Departmental Billing for IRB payment) approval from business office
   - Obtain Data Safety Monitoring Plan (or Charter) from sponsor;
   - Build VOTF (study team) in OnCore;
   - Prepare submission packet: PAF(s);Consents (as required); Protocol and protocol-related documents; Investigator's Brochure; Sponsor's Data Monitoring Charter; IDB; VOTF, (Verification of [CITI] Training Form); and any Safety Reports received from the sponsor;
   - Obtain necessary signatures from Principal Investigator and Department, as required;
   - Enter all documentation into OnCore (initial entry of study into OnCore);
   - Submit protocol to SRC for review and approval;
   - The DSMB reviews the study at this time. If questions are raised or changes required by SRC or the DSMB, they must be addressed by the IRB Coordinator and PI prior to approval;
   - Submit to IRB for study approval;
   - All IIT (Investigator Initiated Studies), NCI funded studies.(e.g., SWOG, ECOG, CALGB, RTOG) and studies involving minors must go through the full local IRB approval process;
   - If also submitting to WIRB (only for Industry studies,) only a "short" PAF form is submitted to the local IRB, who must approve the protocol before submission to WIRB;
Responsibilities of the Clinical Research Team

- Submit PAF to any and all other protocol-specific required committees for approval each study (e.g., IBC, RSC, etc.);
- All questions and/or changes to the protocol documents requested by all the review committees must be fully addressed by the IRB Coordinator and the PI prior to obtaining approval from each Committee;
- Approval is obtained from all the required committees, the study team is notified and approved documents are provided to the study team and the sponsor;
- All approved documentation is entered into OnCore;
- The IRB Coordinator notifies CTO that the Site Initiation Visit may be scheduled and attends this meeting prior to the opening of the study. When study drug is received, the study is listed as "open to accrual" in OnCore and enrollment may begin;

C. Prepares and submits all required changes for IRB (and/or required Committees) during the life of the study.
- Study protocol changes (e.g., amendments, revisions, updates or clarifications as described by the sponsor or PI);
- Consent changes (necessitated by protocol changes, Investigator Brochure updates; or protocol amendments and/or safety reports);
- Safety reports (LSAEs and Industry safety reports);
- Annual review reports for submission and approval.

D. Enters all submissions and approvals into OnCore and notifies the study team (and the sponsor) of any and all protocol changes and approvals; assures that the study team has all current approved documents.

E. Maintains communications with the study sponsor and/or auditors regarding all protocol revisions, updates and safety risk changes and reviews requiring oversight committee approval and/or close-out procedures.

F. Notifies the IRB(s) of termination or study closure and conclusion, coordinates close-out procedures with the sponsor, and provides all required documentation for the sponsor.

G. Closes the study in OnCore.
Attachment 8

Responsibilities: Regulatory Specialist
The Regulatory Specialist prepares and updates all regulatory documentation required by outside regulatory offices and the sponsor's regulatory offices; maintains a constant, open and ongoing communication with the Sponsor/Monitor throughout the study to assure that all changes in personnel, training, licenses and other required regulatory documentation is always up to date, and maintains these records for the CTO office in OnCore.

A. prepares all regulatory documentation for Initial approval and provides the sponsor with required documentation prior to approval of the study, including:
   - VOTF (Verification of [CITI] Training Forms (required for local IRB);
   - CVs and Licenses for all Investigators or Sub-Investigators;
   - Form FDA 1572;
   - Financial Disclosure Form(s) (FDF) (generally study-specific forms);
   - IRB certification and listing of all members;
   - CLIA and other certification for each laboratory used;
   - Normal test values for all tests done at each Lab listed;
   - Delegation of Duty (Authority or Responsibilities as described by the Sponsor);
   - Site protocol training logs as required by the sponsor (required prior to opening a new study).

B. Obtain required signatures from study staff for all required regulatory documents and study logs throughout the study.

C. Maintain and update all UACC personnel CITI training documentation in OnCore.

D. Maintain and obtain current CVs and licenses documentation in OnCore and on each study as staff changes or expirations occur. (This is required for all PIs, Co-PIs and Sub-Investigators.)

E. Maintain a constant dialog with the study representatives to maintain and update regulatory documentation throughout the study, as required by the sponsor and/or regulatory agents.

F. Participate in quality assurance activities (monitoring visits, internal audits, sponsor audits, FDA audits).

G. Assist with the study close-out procedures with all oversight committees and the sponsor and in OnCore.
Responsibilities: Clinical Trials Office (CTO)
The Clinical Trials Office is responsible for providing centralized protocol submission and management of all clinical trials conducted at the University of Arizona Cancer Center. CTO assists the research team in developing, implementing and managing the conduct of clinical trials and maintenance of regulatory documentation compliance. CTO is the liaison for submission of documents to University of Arizona and UACC oversight committees, including SRC (Scientific Review Committee), Institutional Review Board (IRB), Western Institutional Review Board (WIRB), Institutional Biosafety Committee (IBC), DSMB (Data and Safety Monitoring Board).

CTO personnel review submitted clinical trial documents to ensure that all appropriate components are present including study protocol, investigational drug brochure, informed consent form, project approval form prior to distribution for resource or institutional committee review as appropriate.

A. Communication of all study-related issues or problems to the principal investigator, research nurse coordinator, clinical research coordinator or clinical research assistant.
B. Communication with sponsors and CROs regarding site activation, approval processes and regulatory document requirements.
C. Oversight for OnCore development and implementation.
D. Professional conduct in the presence of subjects, research staff, sponsors, monitors, etc.

Specific responsibilities include, but are not limited to, the following:
A. Regulatory documentation:
   • track and store originals and/or copies of all required regulatory documents for clinical research projects;
   • assist with the preparation of IRB submission documentation – protocol re-approvals Continuing (Periodic) Review Forms, Verification of Training Forms and other documents as requested;
   • provide reports and summaries for the monitoring and tracking of clinical study status including approvals, accrual and demographic information;
   • provide updated reports to research team on IRB/WIRB status and submissions.
B. Site evaluation and site initiation visits:
   • coordinate with study sponsors and clinical research organizations (internal and external);
   • provide direction and guidance on the approval process and availability of resources for the conduct of clinical trials;
   • assist with the budget review process, distributing protocols to resource reviewers as appropriate.
C. IRB/WIRB review and approval:
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- support administrative staff in the tracking and routing of project documents in the submission and approval processes;
- act as protocol liaison to committee as appropriate;
- assist in the coordination, preparation and submission of Continuing (Periodic) Review Forms for continuing review of projects.

D. OnCore development and implementation:
- assist with the development of database entry forms and monitoring reports;
- provide training and on-going assistance to database users.

E. Education and training:
- assist in the development and presentation of OnCore specific training sessions;
- coordinate CCRC multidisciplinary bi-monthly meetings held to present Phase I studies (which include new agents for development); to review on-going clinical trials and to announce new potential studies for drug development.

F. CRSS administration and operations:
- coordinate and obtain operating equipment and supplies;
- participate in the distribution of protocol information and materials;
- provide supervisory support.
Attachment 10

Responsibilities: QA/QC Program Monitor
The QA/QC Program Monitor is responsible for monitoring activities for investigator-initiated clinical trials as a continuous review of the conduct of the trial, including adherence to study design and documentation of appropriate reporting of trial data. The monitor oversees that the trial is conducted and documented properly by carrying out routine monitoring duties as identified in the Code of Federal Regulations, the Guideline for Good Clinical Practice, and applicable internal department manuals.

Specific responsibilities include, but are not limited to, the following:
A. Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.
B. Verify the presence of properly executed written informed consent document(s);
C. Verifying that the investigator is enrolling only eligible subjects.
D. Report the subject recruitment rate, if applicable.
E. Verifying that source data/documents and other trial records are attributable, legible, contemporaneous, original, accurate and maintained.
F. Verify that the investigator provides all the required reports, notifications, applications and submissions, and that these documents are accurate, complete, timely, legible, dated and identify the trial.
G. Check the accuracy and completeness of the Case Report Form (CRF) entries, source data/documents, and other trial-related records against each other.
H. Inform the investigator of any CRF entry error, omission, or illegibility (i.e. via the trip report).
I. Determine whether all adverse events (AEs) are appropriately reported.
J. Determine whether the investigator is maintaining the essential documents.
K. Communicate deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator.
L. Document the monitoring visit on the site specific form provided and by signing the monitoring log as applicable.
M. Submit a written report after each trial-site visit and/or reporting trial-related communication (if applicable).
N. Attend QA/QC Program meetings and appropriate conferences, committee(s) and board meeting(s).
Attachment 11

Responsibilities: QA/QC Program Auditor
The QA/QC Program Auditor is responsible for evaluating trial conduct and compliance with the protocol, SOPs, GCP and applicable regulatory requirements.

Specific responsibilities include, but are not limited to, the following:
A. Oversee, develop and perform QA/QC activities;
B. Perform internal audits and reviews;
C. Prepare and submit written audit reports;
D. Prepare and submit to the DSMB quarterly written QA Program reports;
E. Attend and support all Sponsor-initiated audits;
F. Attend and support all FDA-initiated audits;
G. Attend site evaluation and initiation visits;
H. Attend QA/QC Program meetings and appropriate conferences, committee(s) and board meeting(s).