APPENDIX 3 - CLINICAL RESEARCH ROLES

This appendix provides a brief description of the roles of key persons at USC associated with Human Subject Research (HSR), which includes:

- Clinical trials;
- Research using human biological materials;
- Retrospective research involving record reviews;
- Focus group testing or survey research;
- Studies that have IRB approval from other organizations, including approval from other government entities;
- Off-site studies, domestic or foreign, including studies with other government agencies or academic institutions;
- Studies associated with the Food and Drug Administration (FDA), including the FDA's private database information, either alone or in collaboration with another government agency.

CLINICAL STUDY TEAM

Principal Investigator (PI): The PI is responsible and accountable for the preparation, integrity of the design, conduct, and management of the clinical study, assuming full responsibility for the treatment, safety and evaluation of human subjects, and for the integrity of the research data and results. The PI may delegate responsibility to individual members of the research team; however, the PI cannot delegate accountability for the ethical conduct of the study. The PI is also responsible for the direction and oversight of compliance, personnel and collaborators, financial and budgetary management, and for coordination with school, department, and central administration personnel to assure research is conducted in accordance with local, state and federal regulations, as well as USC and sponsoring agency policies and procedures. In clinical trials that are investigator initiated, the PI also assumes the responsibilities of the Sponsor. In addition, the PI is responsible for:

- Ensuring the disclosure of financial interest and arrangements of any member of the research team that may present a conflict of interest to the sponsor, IRB and/or to the study participants.
- Ensuring IRB approval for the study is obtained before any subjects are enrolled.
- Ensuring informed consent is obtained in accordance with FDA regulations.
- Administering the drug or using the device only in subjects under the investigator’s supervision or under the supervision of a recognized sub-investigator.
- Maintaining adequate records of the dispensation of the drug or device.
- Returning unused materials at the end of trial, if applicable.
- Preparing and maintaining adequate case histories documents.
- Maintaining correspondence with the IRB and the sponsor to ensure that both have reviewed protocol amendments, recruitment materials, and the Investigator Brochures (IB) and notifying the sponsor if IRB approval is withdrawn.
• Providing progress, safety, and final reports.

**Co-Principal Investigator (Co-PI):** Co-PIs are key personnel who have responsibilities similar to those of a PI on human studies research projects. While the PI has ultimate responsibility for the conduct of a research project, the co-PI is also obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of research on human subjects.

**Research Coordinator:** Works under the direction of the PI to support, facilitate and coordinate the daily activities of the clinical study. Responsibilities include: supports the safety of clinical research patients/participants; coordinates protocol-related research procedures (e.g., collection of documents for Regulatory Binder), study visits and follow-up care; screens recruits and enrolls patients/research participants; maintains study source documents; reports “Reportable Events” (e.g. adverse events); understands Good Clinical Practice (GCP) and regulatory compliance; educates subjects/research participants and family on protocol, study intervention, study drugs, etc.; complies with institutional policies, standard operating procedures and guidelines; and complies with federal, state and sponsor policies. For studies performed outside of the Clinical Investigations Support Office (CISO), responsibilities of the Research Coordinator also include those of the Regulatory Manager, the Data Manager, as well as submission to, and negotiation with the USC Clinical Trials Office.

**Study Monitor:** The study monitor is responsible for monitoring the clinical study and reports to the study Sponsor. Monitor responsibilities include: performing site visits, and ensuring that adequate and accurate records are kept; all reportable events are recorded; study drugs are accounted for; the study protocol is being followed; informed consent is obtained, and the rate of patient enrollment is meeting established targets, among others. The frequency of site visits and complexity of the monitoring plan depends on a number of factors, such as the complexity of the protocol, the disease being evaluated, the level of experience of the investigator/staff, site performance history.

**Data Manager:** The Data Manager is responsible for set-up and maintenance of the clinical study database, data entry, as well as statistical analysis of study data.

**Sponsor:** A sponsor may be an individual, a private company, an institution or other organization that is responsible for the initiation of a study involving a drug, device, or biologic. The sponsor is always the entity that funds the clinical research.

**Post-Doctoral Scholar:** A Postdoctoral Scholar at USC may qualify as a co-PI but may not be the principal investigator of a clinical trial, unless a specific waiver and approval is granted by the Office of Research and upon recommendation by the Department and approval of the appropriate Dean. Postdoctoral scholars must qualify as a Postdoctoral Research Associate; Postdoctoral Fellow or Postdoctoral Teaching Fellow. The Postdoctoral Research Associate or Postdoctoral Teaching Fellow is appointed as a temporary, fixed-term employee of the University. The Postdoctoral Fellow is registered as a non-matriculated, non-degree seeking, and limited status student of the University. Postdoctoral Scholars must have been awarded a Ph.D. or equivalent doctorate in an appropriate field within five years of initial appointment.

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CLINICAL TRIALS OFFICE (CTO)

Clinical Trial Financial Administrator: The Clinical Trial Financial Administrator is responsible for conducting the Medicare Coverage Analysis (MCA). Through this process the Financial Administrator identifies and differentiates between costs that are study related and should be charged to the study sponsor and those costs that are routine patient care that would occur independent from the study and therefore could be charged to Medicare or third party insurance.

Budget Specialist: The Budget Specialist is responsible for developing and negotiating clinical trial budgets. The Budget Specialist starts working on developing the budget after receiving the Medicare Coverage analysis (MCA) and in collaboration with the Principal Investigator and other administrative participants.

Senior Contract Manager: The Senior Contract Manager is responsible for reviewing, negotiating, and executing the Clinical Trial Agreement (CTA).

CLINICAL INVESTIGATIONS SUPPORT OFFICE (CISO), NORRIS COMPREHENSIVE CANCER CENTER (NCCC)

Regulatory Manager: The Regulatory Manager ensures that the clinical study meets compliance requirements of all local, state and federal regulations, as well as USC and sponsoring agency policies and procedures. Responsibilities include preparing and/or overseeing the preparation of regulatory submissions, including safety reports, amendments, supplements and license renewals, original applications to the FDA (i.e.: Investigational New Drug (IND), Clinical Trial Applications (CTA), New Drug Applications (NDA), Marketing Authorization Applications (MAA), and Biologics License Applications (BLA)). Additional responsibilities may include providing regulatory review of clinical protocols and development documents, ensuring IND/NDA information is updated and maintained in accordance with requirements, and providing strategic regulatory advice to assigned project teams in coordination with Regulatory Affairs management.

OFFICE OF COMPLIANCE

Director of Research Compliance: The Director of Compliance is responsible for performing periodic risk assessments; conducting periodic monitoring and auditing; investigating allegations of non-compliance and recommending corrective action where appropriate.

Research Compliance Manager: The Research manager is responsible for providing training and education on ethical standards, policies, and procedures and assisting in the development of standards, policies, and procedures to prevent and detect violations.
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SPECIAL PROJECTS ACCOUNTING (SPA)

**Manager, SPA Special Projects Accounting:** The SPA Manager is responsible for uploading the Study Calendar, Research Order Form and MCA on to TRUE. Responsibilities also include verifying that Informed Consent and HIPPA documents are uploaded onto TRUE within 24 hours of receiving patient enrollment information from study team, as well as verifying participant care billing (i.e.: ensure billing is made to the appropriate entities – Medicare, sponsor or patient insurance, etc. – and that charges are billed at Medicare rates). For industry-sponsored studies, the office maintains study accounts and processes/pays study-related bills; for non-industry-sponsored studies, responsibilities are limited to verifying patient bills (actual invoicing is done by the appropriate study team member).

OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS (OPRS)

**OPRS Executive Director:** The Executive Director is responsible for establishing Human Subject Protection Program policies for USC as well as identifying and implementing best practices to ensure continued USC accreditation. Additional responsibilities include oversight of USC IRBs as well as the development of educational resources associated with human subjects research.

**IRB Member:** There are four Institutional Review Boards at the University of Southern California (one on the University Park Campus, and three on the Health Sciences Campus). IRB members review and approve human subject research to ensure it is in accordance with Department of Health and Human Services (DHHS), the FDA, and federal and state laws, as applicable. USC IRBs have the authority to approve, disapprove, or suspend human subject research projects, as well as observe, or have a third party observe the consent process and the conduct of the research. No USC faculty, staff, or student may conduct human subjects research without obtaining approval from the appropriate IRBs at either the Health Sciences or University Park Campuses.