University of New Mexico Comprehensive Cancer Center / New Mexico Cancer Care Alliance

STANDARD OPERATING PROCDURE

Clinical Research Office

Title: COMPLETING AN FDA FORM 1572		
SOP No.: 2.5	**Version No.: 6**	**Effective Date: 1-2005**

Owner: NMCCA Clinical Research Supervisor

Name: Kaylee Deutsch

Signature 12/19/17
Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature 3/28/2018
Date

INTRODUCTION AND PURPOSE

This SOP is designed to give direction to UNM Comprehensive Cancer Center (UNM CCC) and New Mexico Cancer Care Alliance (NMCCA) regulatory and research staff regarding how to complete the Food and Drug Administration's form 1572, *Statement of Investigator.*

SCOPE

This standard operating procedure (SOP) defines the procedures for preparing the FDA Form 1572 for review and signature by the Principal Investigator. It identifies administrative accountability of individual team members for fulfilling this regulatory requirement.

APPLICABLE REGULATIONS AND GUIDELINES

US Department of Health and Human Services Food and Drug Administration, May 2010: Information Sheet Guidance for Sponsors, Clinical Investigators and IRBs

REFERENCES TO OTHER APPLICABLE SOPs

N/A

RESPONSIBILITY

This SOP applies to the following investigators and staff involved in the completion of FDA Form 1572 related to clinical studies managed by the New Mexico Cancer Care Alliance and/or the UNM Comprehensive Cancer Center (UNM CCC). This includes, but is not limited to, the following individuals:

Principal Investigator (PI)

Regulatory Coordinator

NMCCA Clinical Research Supervisor

Study Pharmacist

Physician's Assistants, Nurse Practitioners, or other study staff

PROCEDURES

Administrative responsibilities -

. Owner	Criteria / Steps
Primary Regulatory Coordinator	Curriculum Vitae Obtain the current CV from the PI and ensure that the CV is signed and dated on the first page (within 1 year of the current date) by the PI. Save to Regulatory Drive (R:drive)
Primary Regulatory Coordinator	Form 1572 Use the *most current version* of the FDA form 1572, located at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm Check the **expiration date** in the **upper right hand corner**. Prepare the FDA Form 1572 for review and signature by the Principal Investigator. Ensure that all addresses are complete and accurate. Box 1 lists the Principal Investigator and indicates NMCCA after the PI's name. In Box 3, follow current directions to include all sites within the NMCCA network, including UNM CCC, that will play an active role in the study. NOTE: This may include more than one clinical site for which the listed PI will provide oversight. Box 3 will also include drug shipment addresses for each NMCCA affiliate site that is playing a role in the study. In Box 4, follow current directions to include all laboratories within the NMCCA network that will play an active role in the study. In Box 6, include all personnel as required by the sponsor. Submit the completed, signed form to the study sponsor; do not submit directly to the FDA. NOTE: For Investigator Initiated Trials, the sponsor is the New Mexico Cancer Care Alliance. Obtain NMCCA approval by the Executive Director. For studies involving Investigational New Drug applications (INDs), incorporate information from FDA Form1572, with other data as required, into the current version of FDA form 1571 and other application materials. Scan the signed FDA Form 1572 and upload to the centralized electronic study database. Place the original (wet ink version) in the study specific regulatory binder. Update the FDA Form 1572 as necessary, e.g. when the Principal Investigator or co-investigators for a trial is/are formally changed or a change occurs in the participating sites for the study. *Those listed on the 1572 should also properly be delegated tasks on the appropriate delegation of authority log. The PI will delegate all tasks of those not listed on the

	1572 document. If mid-levels (physician assistants, nurse practitioners, etc.) are not listed on the 1572, they will be delegated duties on the delegation of authority log.
NMCCA CRS	Ensure training of Regulatory Coordinators on the preparation and completion of FDA Form 1572.
PI or designee	On an annual basis, update Curriculum Vitae (CV) Sign and date current CV in upper right-hand corner of first page Maintain familiarity with the responsibilities and requirements stipulated on the FDA Form1572 Review, sign and date the FDA Form 1572 as required.
Pharmacist	Refer to the FDA Form 1572 in the electronic database to ensure that chemotherapy orders are signed only by the principal investigator or sub-investigator(s) listed on the signed 1572.