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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: CONFLICTS OF INTEREST IN RESEARCH

SOP No.: 1.4	Version No.: 5	Effective Date: 3/30/2007

Owner: NMCCA Clinical Research Manager

Name: Leslie Byatt

Leslie Byatt
Signature

3/19/18
Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature

3/28/2018
Date

INTRODUCTION AND PURPOSE

The New Mexico Cancer Care Alliance (NMCCA), its investigators and staff are committed to the principal of free, open and objective inquiry in the conduct of oncology research. Multifaceted relationships between NMCCA investigators and Industry exist and often complement research. However, conflict of interest (COI) in research can exist if an investigator has interests in the outcome of the research that may lead to a personal advantage and that might therefore, in actuality or appearance, compromise the integrity of the research.

Conflict of Interest (COI) policies are in place at NMCCA and the University of New Mexico Comprehensive Cancer Center (UNMCCC). These policies protect the safety and well-being of study subjects, ensure compliance with laws and regulatory requirements, and protect investigators who may be exposed to conflict of interest situations during the conduct of research.

This standard operating procedure (SOP) describes the procedures for complying with applicable COI policies at both UNM CCC and non-UNM NMCAA-affiliated sites, including conflicts of interest in the protocol review/approval process and potential financial conflicts of interest.

The term "Investigator", for purposes of the COI policy and this standard operating procedure (SOP), includes principal investigators, co-investigators, and any other person (including staff) who are responsible for the design, conduct or reporting of NMCCA research.

APPLICATBILITY

This SOP applies to all individuals fulfilling the descriptions of Investigator at any NMCCA-affiliated site. This includes faculty, and staff (and their family members) of UNM CCC, non-UNM faculty and staff (and their family members) of the NMCCA, and all other collaborators who are responsible for the design, conduct or reporting of NMCCA-facilitated research.

- NMCCA's COI SOP requires UNM CCC faculty and staff must comply with the UNM's policy E110: Conflict of Interest in Research: http://handbook.unm.edu/policies/section-e/e110.html
- Non-UNM investigators must comply with the NMCCA's Financial Conflicts of Interest in Research Policy (attached).

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 46	Protection of Human Subjects
21 CFR 312.32	IND Safety Reports
21 CFR 312.53	Selecting Investigators and Monitors
21 CFR 312.54	Emergency Research
21 CFR 312.60	General Responsibilities of Investigators
21 CFR 312.66	Assurance of IRB Review
ICH E6 1.55	Definition of an SOP

May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
November 2011	Conflicts of Interest in Research, UNM policy http://hsc.unm.edu/research/coi/unmpolicies.shtml
November 2011	Federal regulations for conflicts of interest, HSC reference http://hsc.unm.edu/research/coi/federalregs.shtml
	UNM CRO Data Safety and Monitoring Plan

REFERENCES TO OTHER APPLICABLE SOPs

SOP 2.7	Submitting a protocol to the IRB of record
SOP 3.1	Interactions with the Institutional Review Board

RESPONSIBILITY

It is the responsibility of research study Principal Investigators, the UNMCCC CRO Operations Manager, and the NMCCA Clinical Research Supervisor to identify individuals who will participate in each research study.

For UNM investigators, is the responsibility of the NMCCA Project Specialist to obtain/maintain Financial Conflict of Interest (FCOI) training records, and to assist investigators in obtaining a Click COI Account, which maintains financial disclosure records for each protocol reviewed by the UNM Human Research Review Committee (HRRC).

For non-UNM investigators, it is the responsibility of the NMCCA Project Specialist to obtain/maintain Financial Conflict of Interest (FCOI) training records, track, and facilitate completion/signature of Non-UNM Financial Conflict of Interest Forms.

It is the responsibility of the NMCCA Regulatory Specialist to assign investigators to research protocols and to submit the protocols to the applicable IRB for review, which includes supplying the applicable IRB with required FCOI disclosure documentation as required by that IRB. For UNM investigators participating in protocols submitted to UNM's HRRC, that process is managed electronically through UNM's Click COI system.

It is the responsibility of the NMCCA Regulatory Specialist to provide NMCCA's annual FCOI disclosure form to the HRRC for each non-UNM investigator participating on protocol reviewed by the UNM HRRC.

It is the responsibility of each investigator to accurately, honestly, and in a timely manner, disclose any potential conflict as described on any respective financial disclosure form, and to timely disclose any change in potential conflict of interest that may occur during their participation in NMCCA trials.

It is the responsibility of the NMCCA Conflict of Interest Committee to review all COI disclosure forms that indicate a financial relationship which meets the definition of a significant financial interest (SFI) and determine if the SFI is related investigator's responsibilities, including PHS-funded research. The NMCCA FCOI Committee will then determine if the SFI is a financial conflict of interest. If there is an FCOI, then the NMCCA FCOI Committee will determine if the FCOI can be managed and will propose an appropriate management plan which will specify the actions that must be taken to manage such FCOI.

It is the responsibility of the Regulatory Specialist to implement/submit to the applicable IRB any NMCCA FCOI Committee-proposed management plan for any investigator's SFI disclosure.

PROCEDURES

Approval of New Studies and Identification of Investigators –
All investigators and covered research personnel must comply with federal regulations governing disclosure of personal, professional or financial interests in a research study that may impact upon its conduct, evaluation or outcome.

Owner	Criteria/Steps
PRMC Chair PRMC Vice-Chair Study PI Executive Director UNM CCC CRO Operations Manager NMCCA CRM NMCCA CRS	PRMC Chair/Vice-Chair: when considering a new study for approval, defer from voting when planning to serve as the PI. Indicate which personnel will serve as main study and site PIs. PI: Communicate to regulatory group those individuals who will participate in a given study Managers, Supervisors and/or Executive Director: assign staff for each study

Study amendments and renewal -

Owner	Criteria / Steps
Primary Regulatory Coordinator	Per the most current Data Safety and Monitoring Plan, submit all administrative study amendments to the NMCCA CRS and scientific amendments to the PRMC Chair for evaluation
NMCCA CRS	If an amendment containing scientific changes is associated with a study for which the PRMC Chair serves as PI, submit the amendment to the Vice-Chair of the PRMC or Medical Director of NMCCA.

Preparation of Conflict of Interest Forms -

Owner	Criteria/Steps
Primary Regulatory Coordinator	Confirm with study PI those individuals (senior medical staff) who will serve as study Co-PI or co-investigators.

Submission of Conflict of Interest Documentation - UNM Investigators

Owner	Criteria / Steps
Regulatory Specialist UNM Investigator	All UNM investigators must have an eClick COI account. The regulatory specialist assigns investigators to a protocol at IRB submission. As part of the IRB review, all investigators must disclose any potential conflicts through the eClick COI system.
HRRC Staff/Pre-Award Staff	If a potential conflict exists, submit documentation to the HSC COI Committee for review and decision prior to IRB submission
Investigator	If contacted by the COI Program Specialist or COI Committee Chair, provide all requested information. Following review by the COI Committee, submit a copy of the COI Committee decision memo to the CRO/NMCCA CRS.
Primary Regulatory Coordinator	Review outcome of COI Committee decision with NMCCA CRS and, as needed, Study PI As directed, include COI Committee language in Informed Consent Forms Include copies of COI Committee decision memos as required for subsequent study applications
Investigator Primary Regulatory Coordinator	If the following occur during the duration of the UNM/NMCCA research, report to the Regulatory Office to facilitate preparation and submission of an updated disclosure form within 30 days after the situation to disclose arises to HSC Conflicts of Interest, UNMHSC Office of Research: New significant financial interest that would reasonably appear to be affected by the research New significant financial interest in an entity whose financial interests would reasonably appear to be affected by the research A new situation which could call into question the investigator's professional commitments in undertaking the research or primary allegiance to UNM A significant change to a previously reported disclosure

COIC Actions and Required Disclosure Updates

Owner	Criteria / Steps
Primary Regulatory Coordinator	Review outcome of COI Committee decision with Regulatory Manager and as needed, Study PI As directed, include COI Committee language in Informed Consent Forms. Include copies of COI Committee decision memos as required for subsequent study applications.

Study Team Primary Regulatory Coordinator	If the following occurs during the duration of the UNM research, report to the Regulatory Office to facilitate preparation and submission of an updated disclosure form within 30 days after the dis-closable situation arises: New Significant financial interest on team member or entity that would reasonably appear to be affected by the research. A new situation that could call into question the investigators professional commitments in undertaking the research or primary allegiance to UNM. A significant change to a previously reported disclosure.

PROCEDURES

Collection and Review of FCOI Disclosure – Non UNM Investigators

All non-UNM investigators and covered research personnel must comply with federal regulations governing disclosure of financial interests in clinical research that may impact upon its conduct, evaluation or outcome.

Owner	Criteria/Steps
NMCCA FCOI Committee NMCCA Project Specialist	Proposed plan… Upon approval of this SOP, all current non-UNM NMCCA investigators will complete the NMCCA FCOI Disclosure form. Going forward, new investigators will complete and sign this form. Expiration dates will be recorded in the NMCCA database, and the NMCCA Project Specialist will manage the annual renewal. Any disclosed SFI will be reported to the NMCCA Executive Director, and a management plan will discussed and executed by the NMCCA FCOI Committee.

Preparation of Financial Conflict of Interest Forms – Non UNM Investigators

Owner	Criteria/Steps
NMCCA Project Specialist	The NMCCA Project Specialist will design and maintain the NMCCA FCOI Form. The NMCCA Project Specialist will obtain completed forms from investigators as part of the credentialing process for all NMCCA affiliates.

Submission of Financial Conflict of Interest Documentation – Non UNM Investigators

Owner	Criteria/Steps
Primary Regulatory Coordinator	The regulatory coordinator will supply completed NMCCA FCOI Disclosure forms to the HSC HRRC, as needed, for any study that is reviewed by the HSC HRRC that has a non-UNM investigator listed as study personnel.
HRRC Staff/ Pre-Award Staff	*If a potential conflict exists, submit documentation of NMCCA FCOI's management plan to the HSC COI Committee for review and decision prior to IRB submission?*
Investigator	If contacted by a member of the NMCCA FCOI Committee Chair, provide all requested information. Following review by the FCOI Committee, submit a copy of the FCOI Committee decision memo to the NMCCA FCOI Committee.

Primary Regulatory Coordinator	Review outcome of COI Committee decision with NMCCA CRS and, as needed, As directed, include COI Committee language in Informed Consent Forms. Include copies of COI Committee decision memos as required for subsequent study applications.
Investigator Primary Regulatory Coordinator	If the following occur during the duration of the NMCCA research, report to the Regulatory Office to facilitate preparation and submission of an updated disclosure form within 30 days after the situation to disclose arises to HSC Conflicts of Interest, UNMHSC Office of Research: New significant financial interest that would reasonably appear to be affected by the research New significant financial interest in an entity whose financial interests would reasonably appear to be affected by the research A significant change to a previously reported disclosure

FCOI Actions and Required Disclosure Updates– Non UNM Investigators

Owner	Criteria/Steps
NMCCA FCOI Project Specialist	Review outcome of COI Committee decision with Regulatory Manager and as needed, Study PI Include/maintain copies of COI Committee decision memos as required for subsequent study applications.
Non-UNM Investigator /Study team member	If the following occurs during the duration of the research, report to the NMCCA FCOI Committee to facilitate preparation and submission of an updated disclosure form within 30 days after the dis-closable situation arises: New Significant financial interest on team member or entity that would reasonably appear to be affected by the research. A significant change to a previously reported disclosure.