CTO Regulatory Process **2011-EAE-01**
Version: 1.0
Effective Date: -1-November-2011

External Safety Report (AE) Memoradum of Understanding (MOU)

Effective Date: **November 1, 2011**

Parties to this MOU:

1) University of New Mexico (UNM) Cancer Center, Clinical Trials Office*
2) New Mexico Cancer Care Alliance*
3) UNM Human Research Review Committee(HRRC)/Human Research Protections Office (HRPO)

Brief Background (see SOP 3.9 for full description):

As of January 2009, the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP) issued guidance clarifying that it is neither useful nor necessary that reports of individual adverse events occurring in subjects enrolled on multicenter trials be distributed routinely to investigators or IRBs at all institutions conducting the research. The NMCCA and its participants, including the UNM Cancer Center have adopted this guidance and will no longer conduct a local review of external adverse events forwarded by National Cancer Institute (NCI) Cooperative Group Research Bases, or Industry Sponsors. The CTO/NMCCA will continue to rely on Data and Safety Monitoring Board (DSMB) determinations, protocol revisions, and Investigator Brochure updates provided by the Research Base(s) and multi-center trial sponsors.

Process:

For multi-center trials, the CTO/NMCCA will no longer submit external safety reports to the HRRC for review, per SOP 3.9: *New Mexico Cancer Care Alliance/UNM Cancer Center External Adverse Event Safety Reports*

1) For NCI cooperative group trials and other (industry or academic center-sponsored) multi-center trials for which the HRRC is the IRB of record, the CTO/NMCCA will submit Data Safety Monitoring Board reports within 30 days of receipt and Investigator Brochure updates as dictated by the IRB guidelines to the HRRC.

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2) CTO/NMCCA regulatory staff will submit DSMB reports via electronic mail directly to the HRPO@salud.unm.edu inbox, with a copy to the Operations Manager, Francine Gachupin (FGachupin@salud.unm.edu).

3) CTO/NMCCA regulatory staff will submit DSMB reports as part of the annual or semi-annual study renewal Continuation Report/Application.

4) Note: If the Western IRB is the IRB of record, DSMB reports will not be submitted to the HRPO.

Signatures:

Mark Holdsworth, Pharm.D., HRRC Executive Chair — Date 11/4/11

Francine Gachupin, PhD, MPH, HRPO Director — Date 11/4/11

*Teresa L. Stewart, MHA, CTO & NMCCA Executive Director — Date 11/8/11