OPERATING PROCEDURE ON IRB-RELATED REQUIREMENTS FOR FUNDING AGREEMENTS WITH NON-FEDERAL ENTITIES:

This procedure implements IRB-related AAHRPP requirements that need to be included in contracts and research agreements we enter into with non-federal entities. Typical agreement types this applies to are funding/sponsorship agreements, Clinical Trial Agreements and any contracts that establish research collaboration or project, regardless if funded or not. If you have doubts if this guidance applies to the agreements you are working on, please check with your supervisor or with UNM's Office of Institutional Review Board (OIRB). ***This procedure does not apply to contracts with federal organizations.***

Use instructions below as a check-list to determine if each section applies to the transaction and the agreement you are working on. Please review each item below for each applicable transaction or agreement and follow the steps that are indicated:

1. **Medical Care for Research Participants:**

For contracts and other funding agreements for studies where there is ***a potential for research-related injury to human participants***, medical costs may become an issue. Any study that involves physical intervention with the participant has the potential for research-related injury. An obvious example is a study where drugs or devices are being tested. A less obvious example may be a study where participants are doing strenuous physical exercise. Whenever there is potential for research-related injury to human participants in the research study, the following applies:

Insert the following sample language into the contract and try to get the sponsor to agree to be responsible to pay for medical expenses:

"Research-Related Injury. [The sponsor] shall be responsible for payment of the actual and reasonable medical expenses incurred in diagnosing and treating any injury, illness, or adverse reaction of a study subject that results from the administration of the study drug [or device] in accordance with the protocol or the proper performance of any Protocol procedure."

FOR CLINICAL TRIALS, ADD:

"[The sponsor] will provide payment to [UNM] for reasonable, unreimbursed medical expenses, including hospitalization, which the institution may incur as a direct result of the treatment of a subject's injuries that directly result from the study drug or its administration during the clinical trial, as determined by [the sponsor] and the principal investigator."

2. **Sponsor's Reporting Obligations:**

Insert the following sample language into the contract to capture sponsor-related requirements to report data and findings that could affect participants' safety or influence

conduct of the study and to ensure UNM's ability to communicate results to study participants:

"During and for a period of at least two years after the completion of the study, [the sponsor] shall promptly report to the investigator any information that could directly affect the health or safety of past or current study subjects or influence the conduct of the study, including but not limited to the study results and information in site monitoring reports and data safety monitoring committee reports as required by the protocol. In each case, the investigator and [the organization] shall be free to communicate these findings to each study subject and the IRB."

3. Plans for Disseminating Research Findings:

Insert the following sample language into the contract to ensure UNM's ability to disseminate results of its research and preclude inappropriate interference by the sponsor:

"[The sponsor] acknowledges and accepts the interest of [UNM] in the non-commercial publication of the results, independent of a positive, negative or null outcome of the study. [UNM] shall be free to use the results of the research and clinical study for its own teaching, research, education, clinical, and publication purposes without the payment of royalties or other fees. [UNM] shall submit to [the sponsor] for its review, a copy of any proposed publication resulting from the research at least thirty (30) days prior to the date of submission for publication, and shall consider in good faith all comments provided by [the sponsor] during that review period. If [the sponsor] determines that the proposed publication contains patentable subject matter which requires protection, [the sponsor] may require the delay of publication for a period of time not to exceed sixty (60) days for the purpose of filing patent applications."

If the contract is for multicenter clinical trial study, we may insert language agreeing to delay publication until the earlier of the multicenter publication, or one year after end of study, but with firm commitment from Sponsor to encourage publication.

OVERALL PRACTICE TIP: If the sponsor provides an alternate language to-be-used in place of what you originally proposed, ask the sponsor if such alternate language has been approved by AAHRPP. If not, impose our language as it is required by our human research protections program accreditation standards.

[THE END]