University of Massachusetts Medical School
UMASS

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Date: April 12, 2012, Updated January 8, 2015

To: Industry sponsors of clinical research & trials at University of Massachusetts Worcester and UMass Memorial Medical Center

Re: Subject Injury Coverage Language in Clinical Trial Agreements and Informed Consent Forms at UMass Medical School

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Thank you for considering UMass as a site for your company's clinical trial.

A critical issue for both UMass and an external sponsor is *subject injury coverage*. In order to be certain that sponsors are aware of the UMass position regarding subject injury coverage, we offer the following for earliest discussion in our partnership:

UMass requires sponsor coverage of subject injury for all industry-sponsored, industry-initiated clinical trials involving investigational drugs or devices. This obligation also may apply to non-profit funders or industry-funded, investigator initiated work at the discretion of the institution. This position reflects UMass' belief that no research participant should bear the financial burden of self-pay, co-payments, deductibles, nor impact on lifetime insurance limits because they have experienced a research injury when participating in the development of products for companies.

This obligation must be incorporated directly into the agreement or through a separate Letter of Indemnification (LOI) from sponsor. Please note that UMass will not agree to the following terms:

- Language that restricts sponsor's injury coverage to 'immediate care' or 'emergency treatment;'
- Language which creates an exception to sponsor's obligations for such coverage based upon a participant's failure to follow instructions or protocol; and
- Language which requires UMass Medical School, UMass Memorial Health Care, Inc. or other health care provider who supplies care in the event of subject injury to first seek payment from participant's insurance or other third party payor.

Additionally, the Informed Consent Form (ICF) must contain language which is congruent with contractual requirements stated above, but cannot contain language that gives the appearance that a research participant waives any legal rights by volunteering for a study in accordance with 45 CFR 46.116, which states:

> ***"No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."***

Therefore, it is the position of UMass Medical School's IRB that legal responsibilities between sponsor and institution regarding subject injury payment are to be addressed in the clinical trial agreement, and not in the ICF. Therefore, the IRB will not approve language containing limitations to sponsor liability based upon site's negligence or wrongdoing or language which appears to do so.

As an institution committed to facilitating industry sponsored clinical trials, we hope this clarity around UMass' subject injury coverage requirements will help us achieve efficient study review and a successful clinical trial partnership.