Thomas Jefferson University – Office of Human Research

Statement of Protection of Research Participant Financial Welfare

The protection of participants in human research is founded on the principles set forth in the Belmont Report and formally encoded in U.S. federal regulations overseeing human research at 45 CFR 46, also known as the Common Rule. These principles are: respect for persons, beneficence, and justice.

Institutional Review Boards (IRBs) are federally mandated to review human research studies and apply the requirements of 45 CFR 46 to ensure that human participants are protected from risk. Risks should be understood not only as physical risks, but also as psychological, social, employment, criminal, and financial risks.

In respecting the rights and inherent dignity of participants, as well as their willingness to give of their time and bodies for the benefit of medical research and advancement, we at Jefferson strongly believe that the costs of managing any research-related injury must not be borne by the participant, when at all possible. This belief is firmly in line with the Common Rule mandate to protect the rights and welfare of participants. If costs must be borne by the participant, this must be clearly described in the research consent form, so that the participant has the opportunity to read and understand these costs, and then decided whether or not they will participate in the study.

Specifically, 45 CFR 46.111(a) Criteria for IRB approval of research, begins with the statement: "In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied." The first criterion is: "Risks to subjects are minimized." If potential adverse events from investigational drugs, devices, and procedures are risks, then certainly, an IRB must consider that if these adverse events are experienced by a participant, the financial burden of managing these adverse events is a secondary risk that is firmly within the purview of the IRB's mandate and must be considered in deliberations when determining whether a study can be approved.

So-called 'carve-outs' imposed by some sponsors are, in our opinion, demeaning to the participant, in direct opposition to respecting the inherent dignity and contribution of the participant, and contravene the Common Rule directive to protect the rights and welfare of participants. Carve-outs are qualifications imposed on sponsor payments for participant injury and include sponsor:

- not covering costs of injury when participant does not properly follow study protocol
- claiming sole right to make determination of whether injury is research-related
- adding qualifications to the term "research-related injury" to dilute its application (e.g., adding "serious" to the term)
- claiming that adverse effects specifically described in the consent form as being research-related should exempt sponsor from bearing financial cost if they should occur, when in fact the specific citation of these adverse effects should eliminate all doubt that the sponsor should be implicated in covering costs for them

- adding any other limiting factor that mitigates coverage of full cost of properly attributed research-related injuries

Thus Jefferson does not permit the above-cited carve-outs in both the research consent form and the research contract. Discrepancies in language between these documents does not represent acceptance of carve-outs and Jefferson reserves the right to require revision to either document to conform to our standards.