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Army Human Subjects Medical Insurance and Reimbursement - Clause

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Colonel Kenneth A. Bertram, MD, PhD
U.S. Army Medical Corps
Director, Congressionally Directed Medical Research Programs
MCMR-PLF
1077 Patchel Street
Fort Detrick, Maryland 21702-5024

Re: Human Use Requirements for Congressionally Directed Medical Research Programs

Dear Colonel Bertram:

We are writing to bring to your attention the rising and broadening concern in the university research community over the US Army Medical Research and Materiel Command's requirements for conducting human subject research. As you know, the Council on Governmental Relations (COGR) is an association of over 145 research-intensive universities in the United States and we continue to hear serious concerns about the Army's change in the management of research-related illness and injury costs from our membership and other research hospitals and institutions.

When we wrote you in late June about the change in Army policies limiting the options for the recovery of costs for the care of research-related injuries or illness, we expressed our concern over the new prohibition against the use of a subject's health insurance. We knew that this prohibition would complicate the development of budgets and, ultimately, the management of clinical trials.

As we predicted, universities have found it virtually impossible to project these costs in their applications - whether for direct care or insurance coverage. They continue to report, with increasing frustration, their inability to find insurance coverage - the most reasonable alternative for budgeting purposes. We have attached a copy of a letter from the University of Colorado Health Sciences Center's insurance broker as just one very telling example of the universities' efforts to be responsive. As the letter demonstrates, the universities have cast a broad net to identify insurance providers. We echo the broker's question - if the Army knows of a company and product that meets its requirement, the universities are prepared to seek an estimate of costs.

In recent months the Army has issued amendments to existing award agreements to include the new medical care requirement. Some universities like the University of South Carolina have found and proposed liability insurance that, unfortunately, specifically excludes direct medical payments. This type of coverage will require the subject to sue to recoup their medical expenses. The negotiations to modify current agreements have dragged on for a number of months and, despite assurances to the contrary, the Army has not yet agreed to cover these

costs on existing agreements. The suggestion that the Army may be unwilling to pay insurance estimates on current agreements simply exacerbates the universities' concerns and adds to a deteriorating confidence and willingness to participate in the Army's programs. We are not required to estimate these costs for any other federal funding agency including the largest supporter of biomedical research, the National Institutes of Health, and have looked for and failed to find a statutory or other legal basis for the Army's requirement.

We believe estimating these costs is not the solution. In the short-term, the Army should simply agree to reimburse the universities for any allowable and reasonable costs for research-related injuries and illnesses without requiring estimates for direct care or insurance in project budgets. This approach achieves the objective of not requiring the subject to use his or her health insurance and avoids direct payments to subjects by the Army itself. Ultimately, we believe the Army should permit access to third-party payers including Medicare/Medicaid and private health insurance providers.

A number of universities submitted proposals in the most recent round of CDMRP competitions with the expectation that they would be able to negotiate a change to this requirement or a modification of the budget to include the costs of care if an award was to be made by the Army. A modification will be critical to permit some state-assisted universities like the University of Connecticut Health Center to participate in the Army programs. State law prohibits the University from making direct payments to subjects so it must seek insurance as its only alternative. But the University of Connecticut, like the University of Colorado, is unable to find an insurance carrier to cover the costs.

The alternative is a change in the requirement. Without such a change, we fear the universities will be forced to decline any new Army awards and, in the future, will choose either not to participate in the programs or only propose very low risk projects to minimize their exposure. We estimate more than 75% of COGR's members will be forced to make this choice in the very near future.

We must arrive at a solution that moves us toward the Army's goal without compromising the research progress. We continue to believe a meeting with members of the Army's CDMRP and Research Compliance staff and representatives from the universities will be useful to determine how we can assist the Army in conducting critical cancer related research in a manner that does not penalize the participants or the universities.

Sincerely,

Katharina Phillips
President

Attachments