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Army Human Subjects Medical Insurance and Reimbursement - Policy

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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:

The Council on Governmental Relations (COGR) is an association of over 145 research-intensive universities in the United States. COGR works with federal agencies and research sponsors to develop a common understanding of the impact that policies, regulations and practices may have on the research conducted by the membership. We are writing to you about the US Army Medical Research and Materiel Command's Congressionally Directed Medical Research Programs' (CDMRP) Human Use Requirements as stated in the recent program announcements and more fully described in the "General Terms and Conditions for Assistance Awards" that govern the CDMRPs.

The CDMRP require that medical care costs for research-related injuries or illness be provided at no cost to the human research participants. The "General Terms and Conditions" outline the requirements for providing care in a recipient-run facility or contracting with another facility for the care, and direct applicants/recipients to review their liability insurance as a vehicle for covering these costs. Under the program guidelines, the costs for health insurance coverage or the direct treatment costs for research-related illness or injury can be included in the project budget. In the past, the problems with estimating and budgeting the costs for research-related injury or illness have been mitigated by the universities' ability to bill these costs to the subject's health insurance. But the February 2002 revisions to assistance award provisions prohibit the use of subject's health insurance for research-related injuries or illness. The latter prohibition from

seeking reimbursement from third-party payers is a significant change in Army policies and raises sufficient concern among the research community for us to bring it to your attention.

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The attached correspondence shows that universities have struggled with these mandates. The temporary relief provided by allowing access to third-party payers is now abrogated by the most recent revisions to the grant terms/conditions and this has raised serious problems regarding university participation in the Army's programs.

A number of concerns have surfaced in discussions among the universities on the most appropriate response to these Army requirements. Most universities report problems in identifying insurance carriers willing to provide insurance coverage. They and the potential providers find it difficult to assess the level of risk, and thus liability and cost, for what is likely to be a small pool of critically ill patients – not healthy research volunteers. Establishing the costs is made more difficult because Medicare/Medicaid-required reimbursement for clinical trial participation including the “diagnosis or treatment of complications” would cover some potential participants but not others. Also, like the federal government, some states require insurers and health service or health maintenance plans to cover the costs associated with participation in clinical trials as well. Institutions in these states cannot accept a prohibition on reimbursement by third party payers.

Some universities have suggested that the Army consider building a reserve fund to cover the costs associated with Army-supported research-related injuries or illnesses – in effect, self-insuring the CDMRP. Another alternative is to have the Army pay the direct costs for subjects not covered by Medicare/Medicaid or state programs. The Army could purchase health insurance coverage for all subjects participating in CDMRP projects thus creating a larger pool and reducing premium costs. Others propose to grant universities access to third-party payers for all human subjects – Medicare/Medicaid covered or not – after full disclosure to the participants.

We would like to have these issues addressed before individual awards and negotiations begin in November/December. We believe a meeting with members of the Army's CDMRP and Research Compliance staff and representatives from the universities may be useful at this time to discuss how we can assist the Army in conducting critical cancer-related research in a manner that does not penalize the participants or the universities.

We will call your office in the next few weeks to set up an appointment at your convenience.

Sincerely,

Katharina Phillips

President

Attachments

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