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
1077Patchel Street
Fort Detrick, Maryland 21702-5024

Re: Human Use Requirements forCongressionally Directed Medical Research Programs

DearColonel Bertram:

The Council on Governmental Relations(COGR) is an association of over 145 research-intensive universities in theUnited States. COGR works with federalagencies and research sponsors to develop a common understanding of the impactthat policies, regulations and practices may have on the research conducted bythe membership. We are writing to youabout the US Army Medical Research and Material Command's CongressionallyDirected Medical Research Programs' (CDMRP) Human Use Requirements as stated inthe recent program announcements and more fully described in the "General Termsand Conditions for Assistance Awards" that govern the CDMRPs.

The CDMRP require that medical care costsfor research-related injuries or illness be provided at no cost to the humanresearch participants. The "GeneralTerms and Conditions" outline the requirements for providing care in arecipient-run facility or contracting with another facility for the care, anddirect applicants/ recipients to review their liability insurance as a vehiclefor covering these costs. Under theprogram guidelines, the costs for health insurance coverage or the directtreatment costs for research-related illness or injury can be included in the projectbudget. In the past, the problems withestimating and budgeting the costs for research-related injury or illness havebeen mitigated by the universities' ability to bill these costs to thesubject's health insurance. But theFebruary 2002 revisions to assistance award provisions prohibit the use ofsubject's health insurance for research-related injuries or illness. The latter prohibition from

seekingreimbursement from third-party payers is a significant change in Army policiesand raises sufficient concern among the research community for us to bring itto your attention.

Theattached correspondence shows that universities have struggled with thesemandates. The temporary relief providedby allowing access to third-party payers is now abrogated by the most recentrevisions to the grant terms/conditions and this has raised serious problemsregarding university participation in the Army's programs.

Anumber of concerns have surfaced in discussions among the universities on themost appropriate response to these Army requirements. Most universities report problems in identifying insurancecarriers willing to provide insurance coverage. They and the potential providers find it difficult to assess thelevel of risk, and thus liability and cost, for what is likely to be a smallpool of critically ill patients – not healthy research volunteers. Establishing the costs is made moredifficult because Medicare/ Medicaid-required reimbursement for clinical trial participationincluding the "diagnosis or treatment of complications" would cover somepotential participants but not others. Also, like the federal government, some states require insurers andhealth service or health maintenance plans to cover the costs associated withparticipation in clinical trials as well. Institutions in these states cannot accept a prohibition onreimbursement by third party payers.

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

Wewould like to have these issues addressed before individual awards andnegotiations begin in November/December. We believe a meeting with members of the Army's CDMRP and ResearchCompliance staff and representatives from the universities may be useful atthis time to discuss how we can assist the Army in conducting critical cancerrelated research in a manner that does not penalize the participants or theuniversities.

Wewill call your office in the next few weeks to set up an appointment at yourconvenience.

Sincerely,

KatharinaPhillips

President

Attachments

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