



DEPARTMENT OF THE ARMY  
HEADQUARTERS, U. S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL  
AND FORT SAM HOUSTON  
2250 STANLEY ROAD  
FORT SAM HOUSTON, TEXAS 78234-6100

REPLY TO  
ATTENTION OF

MCCS-GCI

28 April 2004

MEMORANDUM FOR DEPARTMENTS OF CLINICAL INVESTIGATION

SUBJECT: CIP Research Study Funding

1. Reference AR 40-38, 3-6b(3), CIRO is the approving authority for extramurally funded Clinical Investigation Program (CIP) studies. Extramural funds are funds obtained from sources other than the military medical treatment facility (MTF) where the study is conducted, e.g., funds obtained from the Medical Research and Materiel Command, National Institutes of Health, or non-federal entities. MTF CIP study funds are Program 8 funds. Gifts for specific CIP studies (i.e., conditional gifts) are not authorized, and non-federal CIP study funding will be implemented by a cooperative research and development agreement (CRADA). Federal funds that have been transferred to a non-federal collaborator to support a CIP study will require a CRADA.
2. CIRO, designated as a Federal Laboratory and approval authority, has negotiated Master CRADAs with regularly recurring collaborators. Approved statements of Work (SOWs) may be appended to these master CRADAs in support of specific CIP studies. CIRO will only approve CRADA/SOWs to support officially approved (IRB and Command approval) research studies done at CIP MTFs. A CRADA/SOW may support a specific CIP study conducted at multiple Army MTFs, however, a CRADA/SOW may not support multiple CIP studies, even if closely related.
3. Resources provided for in a CRADA/SOW are to be used for direct support of the research study in question at the Army CIP facility stated in the agreement. Resources in the form of personnel, working at the facility, are required to be credentialed and privileged, depending on professional capacity. Accounting records are to be maintained as stated in the agreement or as appropriate. A CRADA/SOW will cease to exist when a supported research study is terminated or completed.
4. Principal investigators, while not a signatory of the CRADA/SOW will be sent, via email, the final document for concurrence prior to issuance of an approval letter by this office
5. Requests for advice and questions are always welcome at CIRO. CIRO is committed to foster and support AMEDD CIP research. Questions may be referred to COL Lamiell or COL Martin at (210) 221-2511 (DSN 471 -2511).

  
JAMES M. LAMIELL  
COL, MC  
Chief, Clinical Investigation  
Regulatory Office