



DEPARTMENT OF THE ARMY
HEADQUARTERS, U. S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
AND FORT SAM HOUSTON
2250 STANLEY ROAD
FORT SAM HOUSTON, TEXAS 78234-8100

REPLY TO
ATTENTION OF:

MCCS-GCI (40-38a)

1 July 1999

MEMORANDUM FOR DEPARTMENTS OF CLINICAL INVESTIGATION

SUBJECT: Tasks and Reports for Clinical Investigation Regulatory Office (CIRO)

1. Reference AR 40-38, 2-7d(1), 1 Sep 89, CIRO is the approving authority for investigational drug studies. Investigational drug studies submitted to CIRO will be reviewed by CIRO within ten days of receipt by CIRO. The outcome of CIRO review will either be approval, disapproval, or request for revision. Properly revised studies will be expeditiously approved (ten days or less) by CIRO after receipt by CIRO.
2. Reference AR 40-38, 2-7d(2), CIRO is the approving authority for investigational device studies. Investigational device studies submitted to CIRO will be reviewed by CIRO within ten days of receipt by CIRO. The outcome of CIRO review will either be approval, disapproval, or request for revision. Properly revised studies will be expeditiously approved (ten days or less) by CIRO after receipt by CIRO.
3. Reference AR 40-7, 4-9b, 4 Jan 91, CIRO is the approving authority for emergency use of investigational drugs. Emergency use request required information is specified in the regulation. Requests for approval may be submitted by contacting CIRO at voice (210) 221-2511 (DSN 471-2511) or facsimile (210) 295-0244 (DSN 421-0244) during duty hours. After duty hours contact CIRO using digital pagers (210) 759-7156 or (210) 759-7155.
4. Reference AR 40-38, 2-7b, CIRO should review all clinical investigation (CI) research studies and amendments that do not require CIRO approval. CIRO should receive all such studies and amendments from CI activities within 30 days of approval to begin the studies and implement the amendments. CIRO will review these studies and amendments within a reasonable time. CI activities will be notified of any required study or amendment revisions.
5. Reference the 5 Feb 94 memorandum entitled "Policy on the use of animals for medical purposes in U.S. Army Medical Command Programs" issued by MG Cameron, CIRO should receive approved IACUC minutes within 30 days of approval, animal protocols within 60 days of approval, and the USDA annual report by 1 Dec following the end of the report fiscal year (30 Sep). CIRO will review these studies and amendments within a reasonable time. CI activities will be notified of any required revisions.

6. CI study protocol formats and other required documents are specified in AR 40-38, Appendix G, and DoD Directive 3216.2, 17 Apr 95.

7. Reference AR 40-38, 3-6b(3), CIRO is the approving authority for extramurally funded CI studies. Extramural funds are funds obtained from sources other than a military medical treatment facility (Program 8 funds), e.g., funds obtained from the Medical Research and Materiel Command, National Institutes of Health, or non-federal entities. Gifts for specific CI studies are not authorized, and non-federal study funding should be implemented by cooperative research and development agreement (CRDA). Extramurally funded studies submitted to CIRO will be reviewed by CIRO within ten days of receipt by CIRO. The outcome of CIRO review will either be approval, disapproval, or request for revision. Properly revised studies will be expeditiously approved (ten days or less) by CIRO after receipt by CIRO.

8. Reference AR 40-38, Appendix D, CI activities are required to submit an Annual Progress Report (APR). Fiscal year APRs should be submitted to CIRO by 1 Feb following the end of the APR fiscal year (30 Sep).

9. Reference DoD Directive 6000.8, 6.3, 6 Dec 85, CIRO is required to submit an annual report to DoD Health Affairs (HA). CIRO must collect appropriate data for this report. CI activities should submit fiscal year CI data (enclosure) to CIRO by 1 Jan following the end of the fiscal year (30 Sep). CI activities will be notified of changes in the data required for this report.

10. 32 CFR §219 (the common rule) requires a written assurance of compliance with the common rule. This assurance is accomplished for DoD by the Director Defense Research & Engineering. Information required for this assurance is specified in 32 CFR §219.103. CIRO coordinates collection of this data from CI activities. The assurance expires after five years. The next assurance information should be submitted to CIRO by CI activities by 1 Jan 2004. Changes in IRB membership should be reported to CIRO when they occur since information about IRB members is required for the DoD assurance.

11. CIRO should be notified as soon as possible of CI study related serious adverse events and mishaps, CI regulation violations, CI related illegal activities, reports to the OPRR or FDA, and other significant CI problems.

12. Requests for advice and questions are always welcome at CIRO. CIRO is committed to foster and support AMEDD clinical research. Questions may be referred to COL Lamiell at (210) 221-2511 (DSN 471-2511).

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

Enclosure