



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)

27 January 2003

MEMORANDUM FOR CHIEFS, DEPARTMENTS OF CLINICAL INVESTIGATION

SUBJECT: Continuing Review of Human Subjects Research

1. A recent CIRO review of IRB minutes reveals a general lack of compliance with the OHRP guidance on continuing review of human subjects research. Two items in particular stand out: the lack of assignment of a specific date for continuing review, and in some cases, the lack of any mention of continuing review in the minutes.
2. At the latest PRIM&R meeting the issue of assigning a specific date rather than stating that the review will be "annual" was addressed by an OHRP panel. The blanket "annual review" is not sufficient. Guidance on assigning a specific date for continuing review can be found in OHRP's Guidance on Continuing Review (11 July 2002) at: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/Continreview.pdf>.
3. The date for continuing review must be reflected in the IRB meeting minutes. 45 CFR 46.115(a)(2) states, "Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." Hence, the IRB makes the determination that continuing review will be done on "date," and this must be reflected in the minutes.
4. CIRO will continue to monitor these issues and others as we approach the reissuance of DoD assurances for clinical investigation programs. With all that you do right, please continue to improve where possible.

A handwritten signature in cursive script that reads "James M. Lamiell".

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