

REPLY TO  
ATTENTION OF

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

S: 1 March 1994  
26 January 1994

HSMC-GCI (40-38a)

MEMORANDUM THRU Commander, Walter Reed Army Medical Center, Washington,  
DC 20307-5001FOR Chief, Department of Clinical Investigation (HSHL-CI), Walter Reed Army  
Medical Center, Washington, DC 20307-5001

SUBJECT: Human Radiation Research

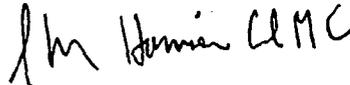
1. At the direction of the Secretary of Defense and The Surgeon General of the Army (Enclosure 1), all pertinent Army medical units will report on research involving radiation exposure of human subjects between 1944 and 1974. Responsibility for regulating reports of clinical investigation for U.S. Army Health Services Command (HSC) rests with the Clinical Investigation Regulatory Office (CIRO) of the U.S. Army Medical Department Center & School (AMEDD C&S).
2. All officers of the federal government are required to take immediate steps to ensure that any documents or records related to human research involving ionizing radiation are retained and not destroyed. This includes all letters, memoranda, reports, logs, handwritten notes, written procedures, and all other writings and other media, such as photographs, maps, and electronic media. Advise all persons responsible for routine document disposal to preserve these records.
3. The records sought are, by definition, at least 20 years old. To secure the confidence of the American people that the Department of Defense has undertaken all reasonable efforts to locate records that still exist, a standardized and thorough effort is required at each pertinent Army medical facility. To document this thorough inquiry, plan to accomplish each of the points of the attached procedure (Enclosure 2).
4. The first step is the designation of a responsible project officer. The project officer will assemble an inventory of existing research records, plus statements from records custodians to indicate the thoroughness of the search for records. Until specific instructions are given for the transfer of records, individual documents will not be removed from their present file series. No records will be destroyed or administratively retired.
5. Common and routine clinical practices (both established diagnostic and therapeutic interventions) involving ionizing radiation are excluded from the present inquiry. But all projects involving the systematic collection of data (i.e., clinical investigations) will be reported and their records secured, since they implicitly question established procedures. Our intent is for you to compile a complete list of titles of all research involving radiation and submit a considerably more limited collection of detailed information regarding exceptional studies (Enclosure 3).
6. Based on your earlier informal responses on this subject, we expect that most of the records you will discover will represent appropriate, ethical medical research. Some of this research will likely have supported the subsequent determination by the Food & Drug Administration that certain radiopharmaceuticals are safe and effective for diagnosis or therapy. Nonetheless, you will disclose all research and clinical investigations from this era involving ionizing radiation.

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7. A Human Radiation Interagency Working Group is coordinating the efforts of all federal departments. Similarly, a DOD working group is also being formed. COL David E. Suttle, MD, GS, is coordinating Army efforts. We will pass on additional or revised requirements from these groups to you as they are issued.

8. Additional information and assistance with preparation of documents may be obtained by contacting MAJ John D. Grabenstein, Regulatory Affairs Pharmacist, at DSN 471-2511 or commercial 210-221-2511.



SHANNON M. HARRISON

COL, MC

Consultant to The Surgeon General  
for Clinical Investigation

Chief, Clinical Investigation  
Regulatory Office

Enclosures