

HSMC-GCI

28 September 1994

MEMORANDUM FOR Director, Radiation Experiments Command Center  
(ATTN: COL Clyde Bailey), 8301 Greensboro Drive, Suite 630,  
McLean, VA 22102 [voice 703-442-5675, fax 703-847-0890]

SUBJECT: Report of Human Radiation Research Between 1944 and 1973

1. This letter responds to a telephonic request from COL Bailey on 23 September 1994 for designation of human radiation exposure under research conditions between 1944 and 1973, inclusive. This response pertains to the Clinical Investigation Program of the United States Army's Health Services Command (HSC), now known as the U.S. Army Medical Command (MEDCOM). MEDCOM is responsible for the delivery of health care to Armed Forces health-care beneficiaries at Army hospitals and clinics in the United States and Panama. The authority for and responsibilities of the Clinical Investigation Program is codified in Army Regulation 40-38.
2. Enclosed is the list of studies identified. They are listed in chronologic order, beginning in 1954 and continuing through 1973. A code book is also provided to facilitate interpretation. Several tables summarizing the data are also provided for your use. These tables vary slightly from previous versions because of more specific data now available.
3. For many of the studies during this time interval, the only extant information is the title of the study, the site, and the approximate date. Information about source documents (including copies of many of the source documents) was provided to you in March 1994.
4. Additional information may be obtained by contacting MAJ John D. Grabenstein, Regulatory Affairs Pharmacist, at DSN 471-2511 or commercial 210-221-2511, fax 210-554-4756.

Enclosures

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Facilities of U.S. Army Health Services Command at which investigational human exposures to ionizing radiation took place using health-care delivery resources (Major Defense Program 8) between 1944 and 1973, based on reports from that facility. We identified no evidence of impropriety in any study.

Data as of: 28 September 1994

General Comment: Corporate policy in the U.S. Army required measures for the protection of human subjects (including informed consent) as early as 1962, two years before the original Helsinki declaration on human research ethics. This policy was more respectful than the norm in comparable civilian institutions.

	Total IR					
	<u>Studies</u>	<u>SE</u>	<u>RT</u>	<u>OG</u>	<u>DTSP</u>	<u>Other</u>
Brooke AMC	9	5	4	1	0	0
Eisenhower AMC	0	0	0	0	0	0
Fitzsimons AMC	17	16	0	0	1	0
Letterman AMC	2	2	0	0	0	0
Madigan AMC	1	0	1	1	0	0
Tripler AMC	2	2	0	0	0	0
Womack AMC	0	0	0	0	0	0
W.Beaumont AMC	8	8	0	0	0	0
W.Reed AMC	<u>30</u>	<u>16</u>	<u>13</u>	<u>7</u>	<u>1</u>	<u>0</u>
Total (1944 to 1973)	69	49	18	9	2	0

Definitions (not mutually exclusive, except DTSP):

IR - ionizing radiation

SE - projects involving radiopharmaceuticals licensed by the FDA at the time of study or investigational radiopharmaceuticals subsequently licensed as safe and effective.

RT - projects involving external-source radiation therapy (e.g., for cancer or thyroid disease) used at a presumably safe and effective dose.

OG - projects involving collaborative oncology groups [e.g., Cancer & Leukemia Group B (CALGB), Gynecologic Oncology Group (GOG), Pediatric Oncology Group (POG), Southwest Oncology Group (SWOG)]. These groups, often funded by the National Institutes of Health (NIH), offer the advantage of centralized review of the science and ethics of projects conducted at multiple civilian and federal hospitals around the country.

DTSP - other projects involving the diagnosis or treatment of sick people to manage clinical disease. Excludes SE, RT, or OG categories.

ISOTOPES USED IN RADIOPHARMACEUTICAL STUDIES  
(1944 to 1973)

Atomic Symbol	Isotope, Salt	1944- 1973	1944- 1994
Am	Americium-241	1	2
Cr	Chromium-51	2	2
Co	Cobalt-57 (in Vit B-12)	0	1
F	Fluorine-18	2	2
Ga	Gallium Citrate-67	11	21
Au	Gold, Unspecified (196?)	1	1
In	Indium-111	4	42
I	Iodide-123 Sodium	3	13
	Iodide-125 Sodium	0	2
	Iodide-131 Sodium	6	26
	Iodine, Unspecified	4	10
P	Phosphate, Chromic, P-32	1	10
Sr	Strontium-89	0	4
Tc	Technetium-99m	11	76
Tl	Thallous Chloride-201	0	10
Xe	Xenon-133	6	7
	Indeterminate or Unspecified	<u>2</u>	<u>50</u>
Total Number of Studies *		50	272

\* - columns do not sum arithmetically, because some studies involved more than one isotope

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ONCOLOGY GROUP PROTOCOLS  
(1944 to 1973)

	Unique <u>Protocols</u>	Iterations of Protocols at <u>Multiple Sites</u>
Cancer & Leukemia Group B (CALGB)	5	6
Gynecologic Oncology Group (GOG)	0	0
Pediatric Oncology Group (POG)	0	0
South Western Oncology Group (SWOG)	2	2
Other Group Projects	1	1
	<u>8</u>	<u>9</u>
Total	8	9