



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



REPLY TO
ATTENTION OF

ARM1.941221.001
(vol. 2)

HSMC-GCI (40-38a)

15 March 1994

MEMORANDUM THRU BG John J. Cuddy, Deputy Commander for Healthcare Operations,
U.S. Army Medical Command (Provisional), Fort Sam Houston,
Texas 78234-6000

FOR Office of the Assistant Secretary of the Army for Manpower & Reserve
Affairs, ATTN: SAMR-HP (COL David E. Suttle, GS), 111 Army Pentagon,
Washington, DC 20310-0111

SUBJECT: Records of Human Radiation Research

1. Revisions to an earlier report requested by the Assistant to the Secretary of Defense are enclosed: Part I and Part II of the request for records involving experiments with human exposure to ionizing radiation within U.S. Health Services Command (HSC) (Enclosures 1 and 2).
2. Part I is the list of facilities queried. The current version of Part II reports answers obtained to date. Part II is not complete, due to the complexity of thoroughly and responsibly searching for records at 60 sites. We will provide you periodic updates of Part II until it completely reflects each medical treatment facility of HSC. Part III consists of the summaries of raw data collected to date (Enclosure 3).
3. Corporate policy in the United States Army required measures for the protection of human subjects as early as 1962, two years before the original Helsinki declaration on the responsible conduct of human experimentation in medical research. Most existing records consist of short entries in annual reports. Few specific records of informed consent have been found, but we have no reason to believe that any volunteer subjects received any unethical treatment of any sort.
4. In compiling the data provided in this report, we erred on the side of inclusion and disclosure of studies involving human exposure to ionizing radiation. If you desire any details not provided here, we seek those answers. For many of the studies described, the only extant information is the title of the protocol recorded in historical summaries.
5. Contact MAJ John D. Grabenstein, Regulatory Affairs Pharmacist, for additional information: DSN 471-2511, commercial 210-221-2511, fax 210-554-4756.

3 Encls

SM Harrison LCMC
SHANNON M. HARRISON
COL, MC
Chief, Clinical Investigation
Regulatory Office

CF: COL Feters, HSC
COL Erdtmann, OTSG
CAPT Jemionek, DDRE



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Part I: Army Medical Treatment Facilities (MTFs)

The following medical treatment facilities in U.S. Army Health Services Command (HSC) have been queried about the existence of records of human research involving ionizing radiation.

Group A. All Army hospitals within HSC that currently operate or previously operated human-use-review and/or clinical-investigation committees (also known as institutional review boards, IRBs), under the human safeguards of Army Regulation (AR) 40-38, Title 32 Code of Federal Regulations (CFR) 219, and 45 CFR 46. Most of these facilities are "teaching hospitals" that train medical, dental, and other interns, residents, and fellows. Clinical research is common at these locations. We believe that these facilities conducted all human research involving exposure to ionizing radiation with appropriate safeguards of scientific scrutiny and under conditions of informed consent.

Brooke Army Medical Center (MEDCEN), Fort Sam Houston TX 78234-6200
Dwight David Eisenhower Army Medical Center, Fort Gordon GA 30905-5650
Fitzsimons Army Medical Center, Aurora CO 80045-5001
Madigan Army Medical Center, Tacoma WA 98431-5454
Tripler Army Medical Center, Tripler AMC HI 96859-5000
William Beaumont Army Medical Center, El Paso TX 79920-5001
Walter Reed Army Medical Center, Washington DC 20307-5001
Womack Army Medical Center, Fort Bragg NC 28307-5000
Martin Army Community Hospital, Fort Benning GA 31905-6006
Keller Army Community Hospital, West Point NY 10996-1197
Letterman Army Health Clinic, Presidio of San Francisco CA 94129-6700

Group B. All other Army hospitals and stand-alone health clinics within HSC (encompassing the United States and Panama). These facilities may or may not have operated IRBs in the past. Each of these facilities currently receives advice and guidance on the ethical conduct of scientific research, as well as human-protection oversight for the purposes of AR 40-38, 32 CFR 219, and 45 CFR 46 from the Army Medical Center in their geographic region. These facilities are listed in sequence by state. It would be quite unusual for these facilities to conduct any form of organized medical research, let alone radiation research. The probability of radiation experiments at these locations is extremely small, but we queried them for the sake of completeness, to assure the American people that all efforts were made to detect radiation experiments.

NOBLE ARMY COMMUNITY HOSPITAL, FORT MCCLELLAN AL 36205-5083
LYSTER ARMY COMMUNITY HOSPITAL, FORT RUCKER AL 36362-5333
FOX ARMY COMMUNITY HOSPITAL, REDSTONE ARSENAL AL 35809-7000
BASSETT ARMY COMMUNITY HOSPITAL, FORT WAINWRIGHT AK 99703-7300
BLISS ARMY COMMUNITY HOSPITAL, FORT HUACHUCA AZ 85613-7040
U.S. ARMY HEALTH CLINIC, YUMA PROVING GROUND AZ 85365-9106
HAYS ARMY COMMUNITY HOSPITAL, FORT ORD CA 93941-5800
WEED ARMY COMMUNITY HOSPITAL, FORT IRWIN CA 92310-5065
EVANS ARMY COMMUNITY HOSPITAL, FORT CARSON CO 80913-5207
U.S. ARMY HEALTH CLINIC, FORT MCPHERSON GA 30330-5000
WINN ARMY COMMUNITY HOSPITAL, FORT STEWART GA 31314-5300
TUTTLE ARMY HEALTH CLINIC, HUNTER ARMY AIRFIELD, SAVANNAH GA 31409-5180
U.S. ARMY HEALTH CLINIC, SCHOFIELD BARRACKS HI 96857-5460
U.S. ARMY HEALTH CLINIC, ROCK ISLAND ARSENAL, ROCK ISLAND IL 61299-7240
HAWLEY ARMY COMMUNITY HOSPITAL, FORT BENJAMIN HARRISON IN 46216-7000
MUNSON ARMY COMMUNITY HOSPITAL, FORT LEAVENWORTH KS 66027-5400
IRWIN ARMY COMMUNITY HOSPITAL, FORT RILEY KS 66442-5037

Part I: Army Medical Treatment Facilities (MTFs)

Group B (continued)

BLANCHFIELD ARMY COMMUNITY HOSPITAL, FORT CAMPBELL KY 42223-1498
IRELAND ARMY COMMUNITY HOSPITAL, FORT KNOX KY 40121-5520
U.S. ARMY HEALTH CLINIC, LEXINGTON BLUE GRASS ARMY DEPOT KY 40507-5106
BAYNE-JONES ARMY COMMUNITY HOSPITAL, FORT POLK LA 71459-6000
KIMBROUGH ARMY COMMUNITY HOSPITAL, FORT MEADE MD 20755-5800
KIRK ARMY HEALTH CLINIC, ABERDEEN PROVING GROUND MD 21015-5131
U.S. ARMY ENVIRONMENTAL HYGIENE AGENCY, ABERDEEN PRVG GRD MD 21010-5422
U.S. ARMY HEALTH CLINIC, FORT DETRICK MD 21702-5000
U.S. ARMY HEALTH CLINIC, FORT RITCHIE MD 21719
CUTLER ARMY COMMUNITY HOSPITAL, FORT DEVENS MA 01433-6401
U.S. ARMY HEALTH CLINIC, SELFRIDGE AIR NATIONAL GUARD BASE MI 48045-5012
GEN LEONARD WOOD ARMY COMMUNITY HOSPITAL, FT LEONARD WOOD MO 65473-5700
PATTERSON ARMY COMMUNITY HOSPITAL, FORT MONMOUTH NJ 07703-5000
McAFEE ARMY HEALTH CLINIC, WHITE SANDS MISSILE RANGE NM 88002-5520
GUTHRIE ARMY HEALTH CLINIC, FORT DRUM NY 13602-5004
U.S. ARMY HEALTH CLINIC, SENECA ARMY DEPOT, ROMULU.S. NY 14541-5001
U.S. ARMY HEALTH CLINIC, WATERVLIET ARSENAL, WATERVLIET NY 12189-5000
REYNOLDS ARMY COMMUNITY HOSPITAL, FORT SILL OK 73503-6300
DUNHAM ARMY HEALTH CLINIC, CARLISLE BARRACKS PA 17013-5003
U.S. ARMY HEALTH CLINIC, TOBYHANNA PA 18466-6083
U.S. ARMY HEALTH CLINIC, FORT INDIANTOWN GAP PA 17003
MONCRIEF ARMY COMMUNITY HOSPITAL, FORT JACKSON SC 29207-5720
DARNALL ARMY COMMUNITY HOSPITAL, FORT HOOD TX 76544-5063
DUGWAY ARMY HEALTH CLINIC, DUGWAY PROVING GROUND UT 84022-6900
TOOELE HEALTH CLINIC, TOOELE ARMY DEPOT, TOOELE UT 84074-5014
DEWITT ARMY COMMUNITY HOSPITAL, FORT BELVOIR VA 22060-5901
MCDONALD ARMY COMMUNITY HOSPITAL, FORT EUSTIS VA 23604-5548
KENNER ARMY COMMUNITY HOSPITAL, FORT LEE VA 23801-5260
RADER ARMY HEALTH CLINIC, FORT MYER VA 22211-5050
U.S. ARMY HEALTH CLINIC, THE PENTAGON, WASHINGTON DC 20310-5801
GORGAS ARMY HOSPITAL, APO MIAMI 34004-5000
U.S. ARMY MEDICAL DEPARTMENT CENTER & SCHOOL, FORT SAM HOUSTON TX 78234

Steps Taken to Locate Records of Human Radiation Exposure

We tasked each of these MTFs with conducting a comprehensive and thorough search for records of human radiation exposure.

Each MTF appointed a responsible project officer to assemble an inventory of existing research records and statements from records custodians. Most MTFs selected the Radiation Protection Officer (RPO) for their activity. The search included at least the following:

- (1) A review of all available annual historical reports.
- (2) Inquiries to senior nuclear-medicine physicians, radiologists, nuclear pharmacists, radiation oncologists, and other appropriate officers regarding the existence of administrative or centralized clinical records.
- (3) Requests for information at meetings of the administrative, clinical, and other appropriate staffs of the MTF.

We further instructed all project officers to take all other prudent steps to identify records and to itemize searches for records that revealed no evidence of human exposure to ionizing radiation.

We initially asked for information from 1944 to 1974. We supplemented this request with a request for an unlimited search for data.

Part II: Locations of Human Clinical Investigations

Section A. Facilities of U.S. Army Health Services Command at which we are confident that no investigational human exposures to ionizing radiation took place between 1944 and February 1994, based on reports from that facility, 15 March 1994

Group A

Dwight David Eisenhower Army Medical Center, Fort Gordon, GA
Martin Army Community Hospital, Fort Benning, GA
Womack Army Medical Center, Fort Bragg, NC
Keller Army Community Hospital, West Point, NY
Letterman Army Hlth Clinic, Presidio of San Francisco, CA

Group B

Bassett Army Community Hospital, Fort Wainwright, AK
Noble Army Community Hospital, Fort McClellan, AL
Lyster Army Community Hospital, Fort Rucker, AL
Fox Army Community Hospital, Redstone Arsenal, AL
U.S. Army Health Clinic, Yuma Proving Ground, AZ
Weed Army Community Hospital, Fort Irwin, CA
Hays Army Community Hospital, Fort Ord, CA
Evans Army Community Hospital, Fort Carson, CO
U.S. Army Health Clinic, Fort McPherson, GA
Winn Army Community Hospital, Fort Stewart, GA
Tuttle Army Health Clinic, Hunter Army Airfield, Savannah, GA
U.S. Army Health Clinic, Schofield Barracks, HI
U.S. Army Health Clinic, Rock Island Arsenal, Rock Island, IL
Hawley U.S. Army Health Clinic, Fort Benjamin Harrison, IN
U.S. Army Health Clinic, Jefferson Proving Ground, IN
Irwin Army Community Hospital, Fort Riley, KS
Blanchfield Army Community Hospital, Fort Campbell, KY
U.S. Army Health Clinic, Lexington Blue Grass Army Depot, KY
Cutler Army Health Clinic, Fort Devens, MA
Kimbrough Army Community Hospital, Fort Meade, MD
U.S. Army Health Clinic, Fort Ritchie, MD
Kirk Army Health Clinic, Aberdeen Proving Ground, MD
U.S. Army Environmental Hygiene Agency, Aberdeen Proving Ground, MD
General Leonard Wood Army Community Hospital, Fort Leonard Wood, MO
Patterson Army Community Hospital, Fort Monmouth, NJ
Bayne-Jones Army Community Hospital, Fort Polk, LA
McAfee Army Health Clinic, White Sands, NM
Guthrie Army Health Clinic, Fort Drum, NY
U.S. Army Health Clinic, Seneca Army Depot, Romulus, NY
U.S. Army Health Clinic, Watervliet Arsenal, Watervliet, NY
Dunham Army Health Clinic, Carlisle Barracks, PA
U.S. Army Health Clinic, Fort Indiantown Gap, PA
U.S. Army Health Clinic, Tobyhanna, PA
Moncrief Army Community Hospital, Fort Jackson, SC
Darnall Army Community Hospital, Fort Hood, TX
Tooele Health Clinic, Tooele Army Depot, Tooele, UT
DeWitt Army Community Hospital, Fort Belvoir, VA
Kenner Army Community Hospital, Fort Lee, VA
Rader Army Health Clinic, Fort Myer, VA
Gorgas Army Hospital (USA MEDDAC - Panama), Panama
U.S. Army Medical Department Center & School, Fort Sam Houston, TX

Part II: Locations of Human Clinical Investigations

Section A (continued)

Based on informal telephone conversations with officers at the following hospitals and clinics of U.S. Army Health Services Command, project officers identified no experiments of interest yet. We still await a written response.

Bliss Army Community Hospital, Fort Huachuca, AZ (Mr. Campbell)
Munson Army Community Hospital, Fort Leavenworth, KS (CPT Megan)
U.S. Army Health Clinic, Selfridge ANG Base, MI (CPT Kaiermeier)
McDonald Army Community Hospital, Fort Eustis, VA (MAJ Smith)

We still await any response from the following hospitals and clinics. We continue to solicit information from these sites.

U.S. Army Health Clinic, Fort Detrick, MD
Reynolds Army Community Hospital, Fort Sill, OK
Dugway Army Health Clinic, Dugway Proving Ground, UT
U.S. Army Health Clinic, The Pentagon, Washington, DC

Part II: Locations of Human Clinical Investigations

Section B. 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 1978, based on reports from that facility. We identified no evidence of impropriety in any study. 9 March 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.

	<u>Total IR Studies</u>	<u>SE</u>	<u>RT</u>	<u>OG</u>	<u>DTSP</u>	<u>Other</u>	<u>Comment</u>
Brooke Army MEDCEN	22	10	9	5	3	0	
Eisenhower Army MEDCEN	0	0	0	0	0	0	
Fitzsimons Army MEDCEN	18	16	0	0	2	0	
Letterman Army HC/MEDCEN	0	0	0	0	0	0	
Madigan Army MEDCEN	11	6	5	5	0	0	
Tripler Army MEDCEN	21	2	6	6	13	0	
Womack Army MEDCEN	0	0	0	0	0	0	
Wm Beaumont Army MEDCEN	10	10	1	0	0	0	
Walter Reed Army MEDCEN	<u>40</u>	<u>18</u>	<u>20</u>	<u>10</u>	<u>2</u>	<u>0</u>	
Total (1944 to 1978)	122	62	41	26	20	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.

Part II: Locations of Human Clinical Investigations

Section C. Facilities of U.S. Army Health Services Command at which investigational human exposures to ionizing radiation took place between 1979 and February 1994, based on entries in the automated Clinical Investigation Research System (CIRS) database. We identified no evidence of impropriety in any study. 9 March 1994

General Comment: Corporate policy in the United States 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.

	<u>Total IR Studies</u>	<u>SE</u>	<u>RT</u>	<u>OG</u>	<u>DTSP</u>	<u>Other</u>	<u>Comment</u>
Brooke Army MEDCEN	136	20	94	89	22	1	ER
Eisenhower Army MEDCEN	40	6	26	24	8	0	
Fitzsimons Army MEDCEN	85	16	63	60	6	0	
Letterman Army MEDCEN (later Health Clinic)	68	22	36	31	11	0	
Madigan Army MEDCEN	78	8	58	54	10	2	ER, XR
Tripler Army MEDCEN	71	8	48	48	15	0	
Womack Army MEDCEN	1	0	0	0	0	1	XR
Wm Beaumont Army MEDCEN	58	21	22	19	15	0	
Walter Reed Army MEDCEN	169	44	90	83	33	0	
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Total (1979 to 1994)	706	145	437	408	120	4	
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GRAND TOTAL (1944 to 1994) (see also Section D)	828	207	478	434	144	4	

Notes:

ER - Evaluation of occupational radiation exposure of ER personnel.

XR - Field tests of new field X-ray equipment for combat hospitals.

Part II: Locations of Human Clinical Investigations

Section D. Facilities of U.S. Army Health Services Command at which investigational human exposures to ionizing radiation took place between 1944 and February 1994, based on all sources of data. We identified no evidence of impropriety in any study. 9 March 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.

	Total IR <u>Studies</u>	<u>SE</u>	<u>RT</u>	<u>OG</u>	<u>DTSP</u>	<u>Other</u>	<u>Comment</u>
Brooke Army MEDCEN	158	30	103	94	25	1	ER
Eisenhower Army MEDCEN	40	6	26	24	8	0	
Fitzsimons Army MEDCEN	103	32	63	60	8	0	
Letterman Army MEDCEN/HC	68	22	36	31	11	0	PD
Madigan Army MEDCEN	89	14	63	59	10	2	ER, XR
Tripler Army MEDCEN	92	10	54	54	28	0	
Womack Army MEDCEN	1	0	0	0	0	1	XR
Wm Beaumont Army MEDCEN	68	31	23	19	15	0	
Walter Reed Army MEDCEN	209	62	110	93	35	0	
GRAND TOTAL (1944 to 1994)	828	207	478	434	144	4	

Definitions (not mutually exclusive, except DTSP):

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

OG - projects involving collaborative oncology groups [e.g., 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 their own clinical disease. Excludes SE, RT, or OG. Includes evaluations of radiographic techniques (e.g., barium enemas), computerized tomography (CT) scans, and other techniques.

ER - Evaluation of occupational radiation exposure of ER personnel.

PD - Preliminary data

XR - Field tests of new field X-ray equipment for combat hospitals.

Part II:

Section D. (continued)

ISOTOPES USED IN RADIOPHARMACEUTICAL STUDIES

<u>Atomic Symbol</u>	<u>Isotope, Salt</u>	<u>1944-1978</u>	<u>1979-1994</u>	<u>Total</u>
Cr	Chromium-51	2	0	2
Co	Cobalt-57 (in Vit B-12)	0	1	1
F	Fluorine-18	1	1	2
Ga	Gallium Citrate-67	10	11	21
Au	Gold, Unspecified	1	0	1
In	Indium-111	3	39	42
P	Chromic Phosphate P-32	1	9	10
I	Sodium Iodide-123	5	8	13
	Sodium Iodide-125	1	1	2
	Sodium Iodide-131	7	19	26
	Iodine, Unspecified	5	5	10
Sr	Strontium-89	0	4	4
Tc	Technetium-99m	15	60	75
Tl	Thallous Chloride-201	3	7	10
Xe	Xenon-133	6	1	7
	Indeterminate or Unspecified	<u>12</u>	<u>40</u>	<u>52</u>
Total Number of Studies *		69	204	273

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

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ONCOLOGY GROUP PROTOCOLS (1944 to 1994)

	<u>Unique Protocols</u>	<u>Iterations of Protocols at Multiple Sites</u>
Cancer & Leukemia Group B (CALGB)	24	27
Gynecologic Oncology Group (GOG)	31	96
Pediatric Oncology Group (POG)	25	62
South Western Oncology Group (SWOG)	86	183
Other Group Projects	59	66
	<u>225</u>	<u>434</u>
Total	225	434

Part III: Source Documents & References

Summary information on 706 clinical investigations involving human exposure to ionizing radiation in U.S. Army Health Services Command (HSC) medical-treatment facilities (MTFs) between 1979 and 1994. Extracted from the Clinical Investigation Research System (CIRS) database. [Additional information is available about each study listed, but only by calling up each study individually.]	Tab A
Report from Brooke Army Medical Center, Fort Sam Houston, TX	Tab B
Report from D.D. Eisenhower Army Medical Center, Fort Gordon, GA	Tab C
Report from Fitzsimons Army Medical Center, Aurora, CO	Tab D
Report from Madigan Army Medical Center, Tacoma, WA	Tab E
Report from Tripler Army Medical Center, Honolulu, HI	Tab F
Report from William Beaumont Army Medical Center, El Paso, TX	Tab G
Report from Walter Reed Army Medical Center, Washington, DC	Tab H
Report from Womack Army Medical Center, Fort Bragg, NC	Tab I
Report from Martin Army Community Hospital, Fort Benning, GA	Tab J
Report from Keller Army Community Hospital, West Point, NY	Tab K
Report from Letterman Army Health Clinic, Presidio of San Francisco CA	Tab L
Reports from Other HSC Hospitals and Clinics	Tab M
Requests for Information (26 + 28 Jan 1994, 15 Feb 1994)	Tab N
Accomplishments of Army Ionizing Radiation Research	Tab O
Army Regulation 40-7, Use of Investigational Drugs & Devices in Humans and the Use of Schedule I Controlled Drug Substances	Tab P
Army Regulation 40-38, Clinical Investigation Program	Tab Q