STATEMENT OF

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DEFENSE NUCLEAR AGENCY

Before The

SUBCOMMITTEE ON HEALTH

COMMITTEE ON LABOR AND PUBLIC WELFARE

U. S. SENATE

November 1971

MR. CHAIRMAN; GENTLEMEN:

I am Dr. John A. Northrop, Deputy Director for Science and Technology, Defense Nuclear Agency. I am accompanied by _____ who is _____ and by _____ the _____. I would like to read a short prepared statement on the subject of the Defense Nuclear Agency's interests in and relationship to research involving humans after which I will be happy to undertake to answer any questions.

Would you note at the start that I am not a medical doctor, but rather have a doctor's degree in physics.

A full understanding of the Defense Nuclear Agency's interest in and relationship to medical research projects begins in 1945. At the same time the world became aware of the awesome power of nuclear weapons, the scientific community became aware of how little was known about the effects of these weapons. In particular, the Department of Defense recognized that the nation needed to know the effects produced by a nuclear weapon on all other components of military systems; the effects on the environment, the effects on materiel, and the effects upon men.

This early recognition of the need for knowledge in nuclear effects was the beginning of vast efforts to learn; but, typical of the opening of new scientific frontiers, were characterized by both a lack of a real appreciation of what was being searched for and also an ignorance of the proper directions for research to take. Additionally, these early

days were noted for the rather rudimentary capability of the scientific instruments employed.

Early efforts to learn of nuclear effects on military systems motivated our first peacetime nuclear test, the Able Shot in Bikini Lagoon in 1946 in which a bomb was simply detonated in the midst of a large array of all kinds of naval ships. Similarly, early efforts to learn of nuclear effects on man saw the Department of Defense testing in operationally realistic tactical problems; exposing troops and animals in tests thought to be reasonable starting points for evaluating the problems of executing military operations in this new environment. You will remember these best by Operation DESERT ROCK in the year 1953 when thousands of Army, Navy, Marine and civilian personnel crouched in trenches, maneuvered across ground zero and provided subjective evaluations of blast, shock and thermal effects while making a myriad of technical measurements.

Now that these tests are nearly 20 years old, the filmed and written records often seem naive, crude and ~~even humorous in the same way that early silent films from Hollywood seem humorous today.~~ OVERLY SIMPLISTIC Nevertheless, these efforts produced identification of some qualitatively gross features of operational problems and identification of specific goals. We found out what the problems really were and thus the tests led to formulation of proper ~~experimental~~ objectives whereby animals could be tested for later correlation of results to humans.

As experience was accumulated, however, the concepts of mass field experiments, even with animals, was abandoned; and this coincides with STUDIES

the period when the Armed Forces Radiobiology Research Institute (AFRRI) was founded. AFRRI has continually improved and developed the specific techniques involved. I should point out here, that this is the normal sequencing of good physical ~~experimentation.~~ INVESTIGATION

~~We now find ourselves at a point where we no longer conceive of human experiments. This is not to deny, however, that~~ That there are still needs for improved correlation of animal ~~experimentation~~ STUDIES results to man and a need to confirm conclusions resulting from animal research. Thus, we have a continuing interest in any medical procedures being carried out for patient therapy whichmight provide information on nuclear weapon effects. To the extent that it does not compromise patient welfare, we ~~capitalize on~~ UTILIZE such radiation therapy ~~treatments~~ to gain laboratory, psychological or clinical information which will improve our understanding of nuclear radiation on man. NEVERTHELESS The overwhelming majority of ~~our work~~ the DNA budget is applied to military hardware, with only about 3½% currently going to investigate the effects of a nuclear environment on man, who still remains a crucial element in military systems.

Thus, Department of Defense funds have been used for many years to gain supplementary research information from ongoing therapeutic programs of medical centers conducted by qualified physicians who are investigating areas of potential significance to national defense needs. The rationale underlying support for such DOD projects has been to obtain data to correlate the biochemistry, psychological and physiological responses of man with the more detailed equivalent data obtained from animal tests. The motivations for obtaining these data are to assist in the prediction of the response of military personnel under conditions of possible operational environments and to provide data which potentially may make possible the

development of treatments of military personnel exposed to such environments or prophylactic treatment before encountering such radiation fields. Such fundamental research data are believed to be potentially useful in treating civilian casualties from any massive nuclear exposure. We should, indeed, be subject to criticism were we to ignore these opportunities for obtaining and evaluating such data inherently available from existing university therapeutic programs.

The Defense Nuclear Agency recognizes that medical research in the United States is in the hands of medical schools, universities, and clinics; and ought to stay there. This leads us to our on-going relationship with the University of Cincinnati.

General guidance on research standards for research contracted for by DNA is provided by DOD Instruction 5030.20, dated May 12, 1964. The DOD does not have its own separate directives on medical ethics. It adheres to the general cultural and national ethics. It is generally accepted that these are set by such organizations as the World Medical Association, American Medical Association, State Boards of Licensure, National Academy of Science and Local Hospital Boards on Ethics and Specialty Treatment Boards.

In 1955, the University of Cincinnati General Hospital ~~began under~~ Dr. Eugene L. Saenger began the development of a radiation therapy project for the treatment of cancer. At that time, it was universally appreciated that there was no successful treatment for advanced and wide-spread cancer, especially when unpredictably distributed in the body. It seemed rational to utilize whole or partial body cobalt-60 radiation for this purpose. Prior studies suggested that this type of radiation treatment might offer a means of ~~control.~~ palliation The entire procedure ~~was~~ has continually been reviewed and approved by knowledgeable

members of the medical faculty at the University of Cincinnati; people unassociated with the study. Patients, all with advanced tumors, were offered this method of treatment; the existence of cancer of this extent was the sole basis for inclusion.

In 1959 an unsolicited proposal from Dr. Saenger to The Surgeon General of the U.S. Army initiated DOD interest in the project. This proposal resulted in a DOD contract funded in 1960 and continuing through this date.

In a similar manner the Defense Nuclear Agency also supports Drs. William T. Hamm and Walter J. Geerate at the Virginia Commonwealth University to determine threshold values for retinal burns. Drs. Maier and Wolfgang at Walter Reed General Hospital have been funded since 1968 to assess the neurological and psychological effects of radiation on the central nervous system of man. In all three of these projects, patients undergo treatment solely on the basis of therapy required by their medical condition.

On 8 October 1971 an article in the news media apparently initiated some misinformed concern that at the University of Cincinnati the Defense Nuclear Agency was sponsoring irradiation of indigent patients to learn the effects of nuclear weapons. This is far from the truth. In actuality since 1960 Dr. Saenger's whole or partial body radiation therapy program has been supplemented by a DOD funded project to obtain detailed data of the clinical and laboratory findings in humans who have received this therapy. These data are basically further blood tests and other

similar tests which are used for comparison to ~~equivalent~~ animal data obtained at the Armed Forces Radiobiological Research Institute. Specifically, the DOD money is used to perform detailed biochemical analysis of hematological and urine samples and psychological evaluation of patients undergoing treatment. At no time was the treatment or its method altered to meet other than the patient's medical needs. The Department of Defense has no say in the selection or medical care of patients or the planning of radiation therapy. The DOD does not support the basic care and patient treatment, that is bed charges, meals, doctors, therapy, etc.; these costs of the University program in therapy and patient care are borne entirely by the General Hospital. No DOD funds have been applied to these costs. The DOD funds are used to pay for additional tests and supplemental laboratory analyses of patients who have received total body radiation therapy. Thus, no patients have received irradiation as a result of DOD funding.

The DOD program was funded under Research, Development, Test and Evaluation, Defense Agencies, for the Defense Nuclear Agency under its Nuclear Weapons Effects Development Program Element 6-27-04H.

Annual Congressional hearings are conducted. Defense Nuclear Agency testimony is presented to the Armed Services and Appropriations Committees of the Senate and the House of Representatives. The Record of the Senate Hearings before the Committee on Appropriations, 91st Congress, Second Session states:

"The major objective is to define and evaluate human response and vulnerability to the effects of nuclear weapons and to prevent, mitigate, or delay that response through improved understanding of the mechanism of injury and advances to prophylaxis, diagnosis, prognosis, and treatment of three basic types of injuries produced and the many variant degrees and combinations that would occur in the free and nonfree environment."

The decision to fund this project at the University of Cincinnati was made because of the existence of the ongoing University of Cincinnati radiation therapy program. The design of the DOD funded portion of the project followed the original proposal by Dr. Saenger as modified by both medical personnel of the DOD and their civilian peers. The current year contract is for $70,000 and the total for the last three years is $244,601. The total funds obligated throughout the period 1960 to the present is $651,482.79. This includes years 1960 and 1961 in which funds were made available through the Office of the Surgeon General, Department of the Army, as well as the funds in all subsequent years provided by direct Defense Nuclear Agency (formerly Defense Atomic Support Agency) contracts. The work has been continued on a year-by-year basis as it was determined that the information obtained was useful to DNA.

To date seven progress reports have been published. They are unclassified and available for open publication from Technical Information Service (NTIS), Department of Commerce, Springfield, Virginia. These data have been available to the public since 1960 and have never been classified. These reports are as follows:

DASA-1422, Metabolic Changes in Humans Following Total Body Irradiation, AD-604,478, Microfiche $.95/Hard Copy $6.00

DASA-1633, Metabolic Changes in Humans Following Total Body Irradiation, AD-467,571, Microfiche $.95/Hard Copy $6.00

DASA-1844, Metabolic Changes in Humans Following Total Body Irradiation, AD-646,667, Microfiche $.95/Hard Copy $6.00

DASA-2179, Metabolic Changes in Humans Following Total Body Irradiation, AD-693,104, Microfiche $.95/Hard Copy $3.00 (after 1 Nov 71 - additional $3.00 service charge)

DASA-2168, Radiation Effects in Man, AD-692,167, Microfiche $.95/ Hard Copy $6.00

DASA-2428, Radiation Effects in Man, AD-714,490, Microfiche $.95/ Hard Copy $3.00

DASA-2599, Radiation Effects in Man, AD-732,025 , Microfiche $. 95/ Hard Copy $ 3.00

Numerous additional publications have appeared in the open scientific literature by various members of the University of Cincinnati group. There has never been anything secretive or classified about the program since the

studies are for the benefit of all citizens and are supported by Federal funds.

In the present therapy program it is recognized that there is no highly successful treatment for such advanced and widespread cancer. Concern has been expressed as to whether patients were truly understanding of the implications of the therapy to which they were agreeing. Each patient was fully informed of the uncertainties of this treatment and was told ~~that the chances of a cure were not large but~~ that it was to slow the growth of cancer. No attempt was made to obtain informed consent until the entire procedure had been explained, twice on two successive days. The patient was asked to bring a relative with him whenever possible. Then the patient was given a statement, which he signed, indicating an understanding of the course to be followed. In most instances one or more members of the family were also advised, and this was always the case when the patient was a minor. ~~Many of the patients were in the hospital at the time and had a chance to consult with other physicians.~~ There was no pressure put upon these patients whatsoever to accept this method. The ~~University of Cincinnati~~ Cincinnati General Hospital is ~~a charity hospital.~~ largely used for the care of indigent patients. Dr. Saenger's patients are characteristic of the general patient population in that hospital. Only those individuals whose general condition was so advanced that no treatment was possible or who declined treatment were not entered into the study. Psychologists interviewing these patients subsequent to the interviews describing their proposed therapy have advised Dr. Saenger that the patients indeed understand the nature and implications of the proposed treatment. These patients

check with Dr. Saenger

in the investigation were, for the most part, at the General Hospital and therefore reflected the general patient population in that hospital. Part of the investigation was to determine the effects of the treatment on intellectual processes. For this it was necessary to establish a baseline intelligence level. The level of intelligence and schooling was simply what was found among those who had this extent of cancer. Patients picked for this study were chosen only on the basis of widespread tumor and not on the basis of intelligence tests. The I.Q.s of patients ranged as high as 115. The lowest I.Q., 61, was in a boy who was mildly mentally retarded. His parents provided consent. In the past three years Each patient was told that the results of the treatment might help soldiers involved in radiation exposure on the battlefield or in exposure to radioactive fallout. ~~This battlefield analogy was made in every case.~~

Research on humans at the University of Cincinnati College of Medicine is reviewed by the Faculty Committee on Research. This Committee is responsible for the protection of the rights of the individual patient and is responsible for the ethical conduct of all research utilizing human beings. The National Institutes of Health of the Department of Health, Education and Welfare requires that each institution doing research work involving human beings have such a Committee and has specific guidelines so that the Research Committee will protect the rights of each patient. The Committee includes physicians not involved in the research project in addition to an attorney and ~~at least one~~ a clergyman, the latter two ~~being in no way~~ not being affiliated with the University. In addition to this impartial reviewing board which examines research annually,

it has also been reviewed yearly by the National Institutes of Health General Clinical Research Committees at both the Cincinnati General Hospital and the Children's Hospital where patients have been treated. Thus, three independent groups review the program and its results regularly for safety and ethics. This completes my prepared statement. I would be pleased to answer your questions.

UNIVERSITY OF CINCINNATI MEDICAL CENTER
FACULTY COMMITTEE ON RESEARCH
VOLUNTARY CONSENT STATEMENT

*I_____ of _____
(Patient) (Normal subject)

being of the age of majority and of sound mind and body, voluntarily and without force or duress, consent to participate in a scientific investigation which is not only directed specifically to my own benefit, but also in consideration for the expected advancement of medical knowledge, which may result for the benefit of mankind.

I have been informed of and understand the nature, duration, and purpose of the study, the method and means by which it is to be conducted, the inconvenience and hazards to be expected, and the effects upon my health and person which may possibly come from participation in the experiment, as follows:

Purpose: To kill tumor cells and at the same time study the effects of radiation on blood and urine.

Procedure: Radiation of the whole body.

Risks: Radiation treatment employed is used to kill tumor cells but at the same time other, normal, cells of your body will be affected. The only cells affected which would cause any risk to you are those cells in your bone marrow. The bone marrow is a "blood factory" where white cells that fight infection, the platelets which help blood clot, and the red cells which carry oxygen to your tissues are made. The bone marrow's ability to make these cells will be decreased for four or five weeks after you receive your radiation. If you receive a dose of radiation of 200 rads or more, which your doctor will tell you, your blood counts will fall to levels where infection or bleeding could be a problem. The bleeding can be treated by transfusion of red cells and platelets and the infection by antibiotics. In addition, we prevent such low blood counts with the use of a bone marrow transplant which will be discussed with you in a separate voluntary consent statement. If your radiation dose is only given to part of the body there is no risk of danger or unusually low blood counts.

I understand that I may, at any time during the course of the experiment, revoke my consent, in writing, and withdraw from the experiment.

I acknowledge that no guarantee or assurance has been made to me as to the results that may be obtained, and I hereby waive any and all claims for liability, except for negligence, on the part of the medical personnel involved, the University of Cincinnati its Hospital and its Medical School, which otherwise might have inured to me or my heirs, as a result of this medical procedure.

I certify that I have read and am competent to understand this consent and that the explanation listed above was, in fact, made.

Volunteer_____ Date_____

Investigator_____ Date_____

Witness (1)_____ Date_____

* Incase of subject under age, the parent or guardian should be the responsible party and should sign on his behalf.

NOTE: Copy to Patient/Normal subject, Research File and Patient's Chart.

FUNDING HISTORY

Project M Budget		DNA RDT&E Budget	% of RDT&E Budget in Project M
FY	$ in Millions		
64	3.6	88.2	4%
65	4.7	116.6	4
66	5.9	102.9	6
67	5.4	98.2	5
68	4.6	108.4	4
69	4.2	112.4	4
70	4.1	115.9	3.5
71	4.1	108.7	3.7

Subtask MC009, Title: Metabolic Changes in Humans Following Body Irradiation

Work Unit 01, Title: Metabolic Changes in Humans Following Total Body Radiation

Investigator: Dr. Saenger, University of Cincinnati

FY	Contract #	Budget	% of M Budget
60	DA-49-146-XZ-029	25,085	
61		30,675	
62		38,800	
63		40,000	
64	DA-49-146-XZ-315	40,000	1%
65		45,000	1%
66		54,640	0.9%
67		61,356	1.1%
68		71,325.79	1.5%
69	DASA 01-69-C-0131	71,369	1.7%
70		80,000	2.0%
71		93,232	2.3%
	TOTAL	651,482.79	
72 (Planned)		~70,000	

Subtask MA 153, Title: Radiation and Human Performance

Work Unit 01, Title: Radiation and Human Performance

Investigator: Col Jack Maier, Walter Reed General Hospital

FY	MIPR #	Budget	% of M Budget
66	527	45,000	0.8%
67	-	0	-
68	540-68	48,296	1%
69	69-515	42,000	1%
70	70-545	40,000	1%
71	71-585	50,000	1.2%
	TOTAL	225,296	

Subtask MB002, Title: Retinal Injury and Flashblindness

Work Unit 01, Title: Rentinal Injury and Flashblindness

Investigators: Drs. Ham and Geeraets, Virginia Commonwealth University

FY	Contract #	Budget	% of M Budget
thru 64	DA 49-146-XZ-102	221,849	
65	DA 49-146-XZ-416	55,000	1.2%
66		83,241	1.4%
67		60,765	1.1%
68		65,000	1.4%
69		70,000	1.7%
70		30,000	0.7%
71		30,000	0.7%
TOTAL		606,855	

Subtask MB 167, Title: Ocular Effects From Intense Light Using Reflectometer

Work Unit 01, Title: Continuation of an Experimentation with a Fundus Reflectometer

Investigator: Dr. Benedict, Technology Inc., San Antonio, Texas

FY	Contract #	Budget	% of M Budget
68	DASA-01-68-C-0149	65,065	1.4%
69		39,321	0.9%
70		39,885	1%
71		54,969	1.3%
		TOTAL 199,240	

Subtask MB 184, Title: Experimental Investigations of Flashblindness Parameters

Work Unit 02, Title: FLas'blindness Parameters

Investigator: Dr. Benedict, Technology Inc., San Antonio, Texas

FY	Contract #	Budget	% of M Budget
70	DASA-01-70C-007	50,075	1.2%
71		47,900	1.2%
72		34,900	0.9%
		TOTAL 132,875	