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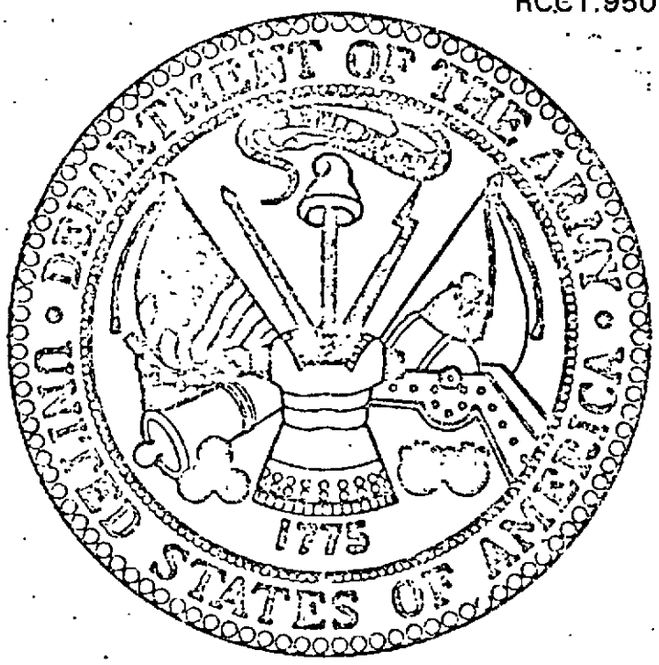

US ARMY ACTIVITY IN THE U.S. BIOLOGICAL WARFARE PROGRAMS

VOLUME I

DRAFT

15 FEBRUARY 1977

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ORIGINAL

U.S. ARMY ACTIVITIES

IN THE U.S. BIOLOGICAL WARFARE PROGRAMS

1942-1977

VOLUMES 1 AND 2

ORIGINAL

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* References are contained in Annex P, Volume 2 and Terms and Definitions are listed in Annex Q, Volume 2.

DA policies and strategic plans. The continuing search for chemoprophylactic vaccines and improved methods for their utilization was no longer structured to meet the requirements for BW defense, but was directed toward the control of communicable diseases in man. In November 1969, President Nixon announced several major decisions concerning the use of biological weaponry, research and stockpiles. BW defense (the mission of USAMRIID immunization and protective measures) research is still authorized. This decision came approximately at the time of the USAMRIID redesignation. USAMRIID research objectiv and ultimate goals are oriented and planned with the reasonable expectations, therefore, that they will benefit the civilian community as well as fulfill a military objective.

Project WHITECOAT. The authorization to allow human volunteers to participate actively as research test subjects provided the basis for a meeti between Army and Seventh Day Adventist Church Officials. Preliminary plans were made to establish the Seventh Day Adventist (SDA) Church membership as a potential resource for Project Whitecoat volunteers. This meeting in Octob 1954 initiated the project that has afforded some 2200 Seventh Day Adventists the opportunity to participate in continuing research at USAMRIID, and an additional 800 to function as laboratory technicians, ward attendants, and at several other significant positions. An official statement of attitude was rendered by the SDA Church indicating offical approval of the project as planned. The SDA General Conference as well as The Surgeon General regarded the services rendered by the volunteers in such a light that a commendatory article, published in the official church newspaper on 3 Novembe 1955, openly indorsed the program by both parties. The article colorfully described the contribution of each "WHITECOAT" with particular reference to service to the country and individual standards of fortitude. This article,

as much as any single action, influenced the theme of the conscientious objector volunteer mission as it relates to USAMRIID. The SDA Project Whitecoat volunteers have provided the Army Medical Department with an extremely valuable and irreplaceable resource and have performed, without question, "Duty the Call of Duty."

Project Whitecoat volunteers were selected from personnel classified as noncombatants (formerly identified by a I-A-O draft status) during their training at Fort Sam Houston. Twice annually, the Commander and Executive Officer, USAMRIID, along with the Director, National Service Organization for the SDA Church, interviewed potential Project Whitecoat volunteers at Fort Sam Houston to select from those interested to volunteer a group of men to be assigned to the unit. Personnel were oriented as a group in order that a common understanding of the general provisions of the program was insured. Potential participants were then interviewed individually to determine the compatibility of their code of conscience and the requirements of Project Whitecoat. If an individual was selected, his reassignment orders were annotated as "earmarked for W/C Project TSG" and personnel reports were similarly modified. Coordination between the Commander, USAMRIID, and the Commander, Medical Training Center (MT advised the latter of the impending visit and requested permission for group presentation and personal interviews.

The above procedure proved effective as long as selective service classification (1-A-O) was prominent data in military records and the special provision of conscientious objector status remained in effect. Coincident with the termination of the draft was the absence of the requirement to provide identification of conscientious objectors, since the theory attendant to a volunteer military force presumed unrestricted assignment policies. The position of the SDA Church concerning the volunteer Army is consistent with past statements of attitude: A noncombatant status must be guaranteed their personnel prior to

entry into military service. To date, a three-year enlistment program as a "volunteer" has been approved by the Department of the Army. This program is now being implemented by the Selective Service System and includes provisions for classifying all interested candidates as 1-A-Os. No Project Whitecoat recruiting has been effected since the discontinuance of the draft.

During the early stages of Project Whitecoat (circa 1959) volunteers participated in several projects, and for the purpose of command and control the volunteers were assigned to the units enlisted detachment. Two hundred spaces were authorized by The Surgeon General to perpetuate Project Whitecoat. This authorization does appear on the TDA. In that all Project Whitecoat personnel are required to complete 91A-AIT Training, the spaces appear as three line items on the TDA: E-5, E-4, E-3 91As. The number of volunteers required was reduced to 177 during 1964. Volunteer projects generally required about two months/year of of Whitecoat's time. During non-project intervals the volunteers performed mission work as laboratory technicians, ward attendants, building systems monitors, and administrative assistants in such a manner that the Institute relied upon their resources for continuity and perpetuation of functions.

The Department of the Army officially set forth the specific regulations for the conduct of research studies in subject volunteers with the publication of AR 70-25 in 1962: Use of Volunteers as Subject of Research. Withdrawal from any particular project and, if the individual so desires, from the entire program, is guaranteed upon request. Desired projects are reviewed thoroughly by the Commander and his staff and forwarded to the Commander, USAMRDC, for final approval as appropriate. The required involvement of high-level personnel insures the proper conduct of experiments administered to human research test subjects.

Of all agencies concerned about the welfare of Project Whitecoat volunteers, it would be reasonable to assume that the Seventh Day Adventist Church would head the list, since the overwhelming majority of Project Whitecoat volunteers are members of the SDA Church. Since the initial attitude statement rendered by the Secretary, General Conference of Seventh Day Advent the position of the SDA Church has remained in favor of Project Whitecoat and voluntary participation of Adventist inductees. Several papers and items of official correspondence have originated from various levels in the SDA hierar unequivocally supporting the research conducted at USAMRIID. In light of the Adventist doctrine that prescribes the strict manner in which the human body should be maintained, the absence of derogatory correspondence from the SDA Church indicates that few complaints have been forwarded to church officials. Occurrences such as those reported in some periodicals would certainly have had a deleterious effect on the strength of Whitecoat volunteers assigned to USAMRIID if any credence were given those reports.

Sample Project Synopsis. The procedures used to initiate and contro the experiments involving human volunteers are organized and disseminated by the Secretary, Medical Division and ultimately become the Standing Operating Procedures which the Commander, USAMRIID will administer throughout the cours of an experiment. The objective, scope, anticipated risk, and special circum stances surrounding a project are prepared by the originating division and Medical Division secretary and are collectively referred to as the protocol o the project. A master bleeding schedule is included as a record of hematolo data accumulated during the experiment since variations in blood chemistry a important in final evaluations. The protocol is reviewed and analyzed at a conference attended by the Commander, Scientific Advisor, and Research Divis Chiefs to refine procedure and determine the potential, foreseeable benefits expected from the research. Once a protocol is accepted by the conference

members and signed by the Commander, it is forwarded to higher headquarters for final approval. A comprehensive distribution list insures maximum utilization of research data and prompt implementation of the findings by the respons divisions. After the approved protocol is distributed, individual volunteers are selected, notified and interviewed. The multipurpose interview provides the volunteers with pertinent and required protocol information, obtains his consent, completes the administration necessary for admission, and consolidate health historical records for review. A final selection process based upon scrutiny of individual medical histories results in the identification of prir and alternate test subjects. This information is provided the Adjutant. Once the health records are screened by the interviewers, they are returned to the Ward Secretary for filing. Master laboratory slips are prepared in duplicate for primary and alternate test subjects and forwarded to the Clinical Laborate Pathology Division for record administration.

On the day of admission, admission sheets are forwarded to Walter Reed Army Medical Center, Registrar Division. Telephonic notification of each primary and alternate test subject is provided, as the WRAMC Registrar in exchange for the Registrar numbers pertaining to the test subjects. Registra numbers are then forwarded to the Ward Secretary. As the admission sheets ar returned by WRAMC, they are incorporated into the patient Clinical Record folder along with the admission card, consent statement, and other pertinent project data.

As the project is completed, narrative summaries are prepared, signed and returned, along with the project charts, to the Medical Division Secretary who transmits a copy of the cover sheet to the Medical Records Library, Registrar Division, WRAMC. Project charts, when completed, are filed in a records area. Master folders containing all project informati

are prepared and reflect the names of participating volunteers, a copy of the protocol, publications referenced, summaries of findings by all investigators narrative summaries pertaining to each individual and copies of information included in the USAMRIID Annual Report. All project information is ultimately summarized by the Chief, Medical Division. The Secretary, Medical Division extracts descriptive project information from the cover sheets and transcribe it into the permanent, continuing list of USAMRIID research projects involvin human volunteers.

Summaries and Source Documents. A list of all studies involving human volunteers conducted by the US Army Medical Research Institute of Infectious Diseases (USAMRIID) and its antecedents, USAMU and WRAMU is found at Table 1. The individual medical records of all volunteer subjects who partic in these studies are on file at USAMRIID as are the records of the individual projects.

An attempt has been made to identify all extra-mural contracts associate with the USAMRIID program since its inception, Table 2. The participation of volunteers is indicated as known. Regulations governing routine retirement an destruction of extra-mural contract records preclude a definitive statement on this aspect.

All publications in the open scientific literature relating to human volunteer studies conducted by USAMRIID through 1972 have been listed, Table Since the inception of this type of research efforts have been made to insure that information of value to the general scientific community be published in appropriate journals.

Vaccines studies developed or under study have been included in a separat list, Table 4.

Source materials relating to each of the summaries described above are on file at USAMRIID, Fort Detrick, Maryland.