

ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE
DEFENSE NUCLEAR AGENCY
BETHESDA, MARYLAND

SUBJECT: Minutes of the Twentieth Meeting, Armed Forces
Radiobiology Research Institute Board of
Governors, 13 April 1972

1. Attendees:

Hq, Defense Nuclear Agency

LTG C. H. Dunn, Director
Dr. J. A. Northrop, Deputy Director, Science & Technology
Mr. P. H. Haas, Scientific Assistant to DDST

Service Representatives:

ARMY

BG R. B. Taylor, Special Assistant to the Surgeon General
for R&D

NAVY

VADM G. M. Davis, The Surgeon General
RADM R. E. Faucett, Asst. Chief for Research and Military
Medical Specialties, BUMED

AIR FORCE

BG G. L. Hekhuis, Director, Professional Services, OTSG

AFRRI

CAPT M. I. Varon, Director
COL L. R. Stromberg, Deputy Director
LT COL J. W. Cable, COR
LT COL J. E. West, Chairman, Radiation Biology Department
Dr. S. J. Baum, Chairman, Experimental Pathology Department
Dr. W. F. Davis, Chairman, Behavioral Sciences Department
Mr. Robert Carter, Chairman, Physical Sciences Department

2. General Dunn opened the meeting at 0900 hours, 13 April 72, and expressed his appreciation for the continued support of the AFRRI by the three medical services. He noted that, during

his recent presentation before the House Armed Services Committee, Congressman Hall, having heard about the change in direction of the AFRRI program, indicated he thought the AFRRI had "turned the corner." General Dunn indicated he was especially anxious to maintain the momentum of this change with continued medical service interest and support.

3. Captain Varon began the formal part of the meeting with a summary of the Joint Medical Research Committee Meeting of 30 March 1972. First, he outlined the isotope research program initiated with the staff of the Isotope Clinic at Walter Reed General Hospital.

Admiral Davis asked about the AFRRI's capabilities in pharmacologic chemistry, both in terms of facilities and manpower. Captain Varon responded by indicating that the Institute's capabilities in this area were being expanded and that additional manpower was programmed to augment the Institute's existing staff.

Admiral Davis emphasized the importance of coordinating with the appropriate government agencies during the early stages of this radiopharmaceutical research program.

General Taylor, expanding on Admiral Davis's point, noted that specific DoD requirements exist controlling the development and use of all drugs, including radiopharmaceuticals prior to their use in human diagnosis and therapy. Captain Varon assured the group that any radiopharmaceuticals developed or produced at the AFRRI would be used in patients only after being cleared by the user through the review board of the NNMC or other appropriate medical facility.

Admiral Davis, emphasizing what he thought to be the tremendous potential at the AFRRI to participate in a radiopharmaceutical program, reemphasized the critical need to obtain the necessary cooperation and assistance from other agencies and professional groups.

Dr. Northrop indicated that, as he understood the extent of the AFRRI's proposed involvement in the radiopharmaceutical area, there were four potential phases. The first involved the development of research protocols; the second, the development of the capability to perform the desired research; the third, performance of the research, and the fourth, those actions relating to eventual approval of pharmaceutical materials for test and/or use in humans. In connection with these points, Dr. Northrop raised the question as to whether the expertise necessary to perform in these several areas, excluding phase four, should be developed at the AFRRI. He questioned whether

or not they might more appropriately be developed in NNMC with NNMC people simply performing at the AFRRRI with AFRRRI's assistance. He stated specifically that insofar as step four was concerned he felt this to be the purview of the separate medical services, and not a responsibility to be undertaken by the staff of the AFRRRI.

Admiral Davis indicated that in his judgment phase one would involve AFRRRI personnel as well as other interested groups, that step two should be one for which the AFRRRI was responsible; i.e., the development of the capability to perform required research and finally that AFRRRI assistance with other groups should be extended to include step three. Admiral Davis concurred with Dr. Northrop in the appropriateness of the medical services having responsibility for the coordination eventually required to use pharmaceuticals developed with AFRRRI assistance in humans and that the AFRRRI would not be involved in phase four.

In regard to research involving patients, General Dunn indicated that he did not feel that the AFRRRI should be primarily involved in such research. However, he expanded on this to say that he had no objections to and indeed he favored the AFRRRI's support of other groups who had a clear mission to do research in problems of human diagnosis and therapy.

In regard to the expansion of the AFRRRI program into other than nuclear weapons effects research, Dr. Northrop indicated that it would be necessary for the services to provide both personnel and dollar assistance if these programs were to become major long term efforts at the AFRRRI. Dr. Northrop indicated, however, that he would be prepared to assist in the initiation of such programs, although he could not be responsible for their sustained support.

General Dunn indicated that he thought it was essential to develop a clear agreement that would delineate AFRRRI's areas of responsibility in support of outside service or facility users.

General Hekhuis indicated that any such agreement should extend to coordination with other government and non-government agencies.

General Taylor specifically stated that he thought it was especially important for AFRRRI to coordinate with other groups including NIH to insure that any review, e.g., by GAO, would demonstrate the adequacy of inter-government coordination.

Captain Varon next described the work of CDR Rish, MC, USN, Neurosurgery Services, National Naval Medical Center, and CDR Brannon, MC, USN, Chief, Neurology Service, National Naval Medical Center.

General Hekhuis asked why, considering AFRRI's mission of Radiobiology, was a microsurgical/neurosurgical training capability being developed.

Dr. Varon answered that CDR Rish's program developed as an extension of the AFRRI's basic interest in neurobiological problems. There are neurobiological problem areas, not being studied by the Armed Forces, which have clear cut military significance. Head injury is a prime example, and CDR Rish's program is correlated with this basic problem area.

Dr. Northrop asked how many man-hours were to be absorbed in provision of support to Drs. Rish and Brannon, adding that he felt that this kind of support should not be supported by DNA/DDR&E funds.

Colonel Stromberg answered, explaining that programs such as Dr. Rish's are being performed on a reimbursable basis, including all overhead, and that RDT&E funds are not used. Certain equipment purchased by RDT&E funds for other programs are made available to Dr. Rish for his use if not otherwise required. This avoids purchase of duplicate equipment.

Admiral Davis indicated that work of the type described would be funded out of O&M clinical investigation funds.

Dr. Northrop indicated that while he was anxious to see AFRRI's program expand in the direction being described, he felt that the position taken by Admiral Davis was wholly appropriate.

Admiral Davis asked whether or not AFRRI's Comptroller capability was such that we knew which funding designations were appropriate to the various kinds of work that we were undertaking?

Mr. Haas interjected, "No", indicating that he felt the responsibility for this kind of funding control should be exercised by HQ DNA Comptroller.

During additional discussions on funding, Dr. Northrop indicated that he felt that the direction of the AFRRI program was such that the Institute would eventually have to move toward industrial funding.

Colonel Stromberg stated that action had already been initiated by the AFRRI Comptroller to investigate and plan

this change in the funding approach, and that in view of the limited Comptroller capability at the AFRRI, support from the Comptroller, HQ, DNA, particularly during the early phase of setting up multiple funding, would be required.

Captain Varon then summarized the preliminary work of Dr. Catravas on the effects of opiates on central nervous system enzymes.

General Taylor indicated that if this particular program was found to be consistent with the needs of the Army, he would help fund continued research in this area.

Captain Varon then described the AFRRI's new program on laser effects on visual acuity.

In connection with this program, General Taylor emphasized the importance of coordination with the U. S. Army's laser program at Frankfurt Arsenal.

Following Captain Varon's JMRC presentation, General Dunn indicated that what he hoped for was an expression from the Board of Governors as to the appropriateness of the direction in which AFRRI was moving in terms of its broadened research mission. He indicated that if the Board of Governors did feel this direction was appropriate, DNA would undertake administrative actions necessary to facilitate such research.

The Board agreed that the collaborative efforts described were appropriate.

4. Mr. Carter then gave a brief presentation on the present status of the EMP program.

Mr. Haas indicated that AFRRI research in this area was absolutely critical, considering the DoD's interest in EMP effects. He further indicated that what he was hoping for was an expression from the Surgeons General on the appropriateness of the approach proposed by AFRRI to study EMP effects.

Captain Varon then outlined the scientific rationale behind the AFRRI approach to EMP, giving a brief resume of the experimental design and objectives.

Admiral Davis emphasized the need for AFRRI to extend its EMP research beyond the consideration of tumor related effects alone.

5. Colonel Stromberg then presented background information related to the request to AFRRI to update a triservice document, TB MED 246 on medical management of nuclear casualties.

Following discussion of Colonel Stromberg's presentation, it was agreed by the Board that the AFRRI undertake the necessary rewriting.

General Dunn agreed that this was clearly within the mission of DNA and agreed that AFRRI should respond to the request for rewriting the tri-service document.

6. The Director, AFRRI, reviewed the NIH and NNMC proposals for human exposure work at AFRRI.

General Dunn indicated that he did not feel it was appropriate for DNA to get involved in the treatment of humans, but if others who are in that business wish to make use of AFRRI facilities, that was wholly acceptable.

Admiral Davis agreed with the position taken by General Dunn and emphasized that the AFRRI is the best location in this area for such work, although it must be understood that the AFRRI's assistance would be limited to a support role, providing services not otherwise available.

General Dunn indicated that while he was prepared for the AFRRI to provide the necessary assistance, it would only be provided when the Board of Governors had approved the appropriateness of the research itself, down to and including specific details and provisions of any protocols and agreements developed in connection with the proposed research.

General Hekhuis indicated that, based on his experience, it might be necessary for significant facilities modification to be undertaken in order for AFRRI to perform the proposed human exposures.

Dr. Northrop emphasized the need to develop a clearly written agreement that stated the responsibilities of the AFRRI and outside users.

General Taylor proposed that a formal agreement be established between the Director, DNA and one of the Surgeons General, providing for direct technical supervision of AFRRI participation in such programs. General Taylor felt that since the DoD does not have guidelines and regulations which cover these programs in detail, it is necessary that the AFRRI programs be reviewed and supported by an agency which does. He suggested that, because of the location of the AFRRI on the grounds of the National Naval Medical Center, the most logical reviewing authority would be the Surgeon General of the U.S. Navy.

Admiral Davis agreed with this concept.

In connection with General Taylor's proposal Dr. Northrop asked whether or not it was necessary for a single set of rules to be established under which AFRRRI would operate; i.e., the Navy's rules, the Army's rules, etc. or whether or not the rules of the group sponsoring a given research project could be followed. He further asked whether or not General Taylor felt that the DoD would be developing regulations applicable to the specific support under question.

General Taylor indicated that he did not think the development of DoD wide regulations was underway but that instead the regulations of one of the individual services would have to be followed. He felt that a single set of rules for all projects would be the best. The three Services all have basically the same rules and regulations and any substantive differences could be handled by a specific agreement if required for any particular research project.

General Dunn indicated that as he understood it, the Board of Governors agreed with the desirability of AFRRRI participation in medical/clinical support activities and that the Director, AFRRRI should proceed with the coordination required in order to provide such support; and finally, that the procedures and regulations of the Department of the Navy would be followed as a guide for AFRRRI support activities.

Dr. Northrop asked whether VADM Davis had any suggestions as to the kinds of groups outside of DoD or NIH that might review proposed AFRRRI involvement in human irradiation work.

Admiral Davis indicated that he thought it was appropriate that the Research Council of the National Academy of Sciences review this particular project and that this Council would be contacted by Admiral Faucett at the appropriate time so that it would be included in the agenda of an early meeting.

Insofar as obtaining of AEC concurrence for facility license modification, General Dunn indicated he thought coordination with OTSG, USN, NIH, and the AEC should go on simultaneously.

Admiral Davis indicated that insofar as NIH use of AFRRRI facilities was concerned, he was confident that they would agree to provide the necessary funds required to modify the facilities.

7. Colonel Cable presented the DNA position on the work done by Dr. Saenger of the University of Cincinnati.

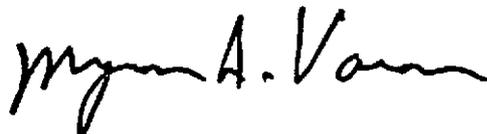
General Taylor indicated that the problems that had developed in connection with the Saenger work were problems which might well have developed in connection with work the Army is supporting in connection with research on hepatitis. He indicated that the response to the Saenger work was simply part of a change in the national attitude toward "people used in research."

General Dunn indicated that, notwithstanding the response from the public and the Congress, DNA felt that the work being performed by Dr. Saenger was necessary work and that it would continue to fund that work through 1973, if this is acceptable to the University of Cincinnati.

8. In summarizing the meeting, General Dunn again expressed his appreciation for extremely gratifying response of the three medical departments to the Board of Governors' decision that the AFRI mission be broadened. He was especially appreciative of the personal interest evidenced by the Surgeons General in the program.

Admiral Davis and General Taylor agreed that remarkable progress had been made by AFRI in diversifying its program and that they felt confident that this was the direction of AFRI which should continue.

9. The Board adjourned at 1230 hours.



MYRON I. VARON
Captain, MC, USN
Surgeon