DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, D.C. 20314

MEDPS-PO

2 July 1970

Isotopes Branch
Division of Materials Licensing
U. S. Atomic Energy Commission
Washington, D. C. 20545

Gentlemen:

Four research protocols are forwarded for your information and appropriate action from Fitzsimons General Hospital, Denver, Colorado.

Recommend AEC License Number 05-00046-13 for this medical facility be amended to include these research procedures.

The radiological hygiene procedures forwarded for renewal of this license, dated 24 April 1969, are still current.

Sincerely,

James E. Anderson

JAMES E. ANDERSON
LTC,MSC
Preventive Medicine Division

4 Incl
as

A/61

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16753

DEPARTMENT OF THE ARMY
FITZSIMONS GENERAL HOSPITAL
DENVER, COLORADO 80240

MEDEO-X

9 June 1970

SUBJECT: Protocol Submitted for License for Use of By-Product Materials

THRU: Commanding General
Fitzsimons General Hospital
Denver, Colorado 80240

TO: The Surgeon General
ATTN: MEDP-P
Department of the Army
Washington, D. C. 20315

Protocol titled "Application for Medical Research Project, The Diagnosis of Functioning Metastasis from Thyroid Carcinoma with I-131 and Scintillation Camera" is submitted for your approval.

Eugene T. Morita

1 Incl
Protocol

EUGENE T. MORITA
Major, MC
Chief, Nuclear Medicine Service

16753

SUBMIT IN DUPLICATE

APPLICATION FOR MEDICAL RESEARCH PROJECT
(OTSG Administrative Letter 70-4)

DATE

TO: Commanding General
Headquarters, U. S. Army Medical Research and Development Command
Washington 25, D. C.

FROM: Nuclear Medicine Service
Fitzsimons General Hospital
Denver, Colorado 80240

TITLE OF PROJECT: The Diagnosis of Functioning Metastasis From Thyroid Carcinoma With I-131 and Scintillation Camera

1. ESTIMATED TIME WORK WILL BEGIN

2. PROBABLE DURATION OF PROJECT: 3 years

3. NAME OF RESPONSIBLE INVESTIGATOR *(Append Biography, SG Form 68-1)*: EUGENE T. MORITA

4. OFFICIAL POSITION AND TITLE: Chief, Nuclear Medicine Service

5. GRADE: Major

6. PROFESSIONAL ASSISTANT(S) *(Append Biography(s), SG Form 68-1)*

7. OTHER CURRENT RESEARCH ACTIVITIES OF RESPONSIBLE INVESTIGATOR

None

8. BACKGROUND AND PURPOSE OF STUDY

Pochin has shown that approximately 80% of the patients with metastatic differentiated thyroid carcinomas, after ablation of their normal thyroid gland, will have function induced in metastases. It is clear that surgery is the mainstay of therapy in patient with thyroid carcinoma; however, the use of radioiodine for treatment of functioning thyroid metastasis has been generally accepted. The difficulty with treatment of thyroid carcinoma is in defining the presence of functioning tumor tissue. According to Pochin's calculation, extremely small amounts of functioning thyroid carcinoma may be found with the use of radioiodine. The work done by Catz, Pettit, and Starr[1] has shown that thyroid stimulating hormone (TSH) stimulation and doses of up to 5 mCi of I-131 have been necessary in order to find small functioning thyroid metastases. They showed several examples in which no areas of uptake had been noted on smaller doses. The use of I-131 in diagnostic doses after thyroid ablation by surgery and/or I-131 appears to be warranted, since delay of treatment may allow progression of the disease It is the purpose of this study to use up to 2 mCi of I-131 in such patients for the diagnosis of functioning areas of thyroid carcinoma.

The purpose of this clinical research protocol is to compare the results of the following methods in finding functioning thyroid metastases:

a. PBI-131[2]
b. Total body scan as done with the scintillation camera.
c. Finding of functioning tumor after therapeutic I-131 and comparing results with # b.
d. Urinary excretion rates of I-131[3]

APPLIC. ON FOR MEDICAL RESEARCH PROJEC (CONTINUED)

TITLE OF PROJECT The Diagnosis of Functioning Metastasis From Thyroid Carcinoma With I-131 and Scintillation Camera

9. METHOD OF PROCEDURE (Include observations to be made in each case)

MATERIAL AND METHODS: All age groups will be included in this study. Pregnant women will be excluded. 1 to 2 mc of I-131 will be given orally to these patients for diagnostic purposes. It will be obtained from a manufacturer who has been approved in our license number 05-0046-13 and material will be administered in the routine manner used for all diagnostic doses. Those who will receive 1 to 2 mc of I-131 will have been rendered athyreotic either by surgery or ablation of their normal thyroid with I-131. The following procedure will be carried out in those patients with thyroid carcinoma:

a. Prior to their evaluation, all thyroid medication and other drugs which will interfere with their study will be discontinued.

(1) Patients on dessicated thyroid or similar thyroid preparations will stop their thyroid 3 months prior to their scheduled appointment.

(2) Patients who are or Triidothyronine or similar preparations will discontinue their medication 3 weeks prior to their scheduled appointment.

b. On the day of their appointment, clinical evaluation will be made with respect to their level of hypothyroidism and to ascertain if there is evidence of recurrent tumor. If they are not yet hypothyroid, they will be rescheduled in one to two weeks or will be given thyroid stimulating hormone (TSH) for 3 to 4 days (5 to 10 units per day). If it is extremely uncomfortable or inconvenient for the patient to be transiently hypothyroid for their evaluation, these patients will be studied while on thyroid. However, they will be given TSH as mentioned above. Baseline studies before I-131 administration include CBC, T3, T4 resin, T4 column, PBI 131 (done to determine if any residual PBI 131 is circulating) and achilles reflex time. A routine chest x-ray will also be included in the evaluation.

c. Following the steps noted in #b, the patients will receive 1 to 2 mc of I-131 orally. The determination of the exact dose will be made by the staff on the clinical grounds. For example, if the patient is markedly hypothyroid and is known to have functioning tissue, he will be given a lower dose.

d. Urines will be collected in 24 hour aliquots for about 3 days, or until excretion is minimal. The purpose of this method is to evaluate the concept that urine I-131 activity should fall off exponentially; a straight line on semilog paper should occur if the patient does not have any functioning metastasis.[3]

e. 24 hours after the oral ingestion of I-131, the entire body will be imaged with the use of the scintillation camera with the high energy 1000 hole parallel collimater in place.[4] Each area imaged will be studied for 15 to 20 minutes in order to obtain sufficient counts to insure good counting statistics. The areas routinely covered by the detector will be the neck and upper chest, chest abdomen and pelvis. If any other areas are clinically suspicious, they will also be imaged by the same method. If areas are localized on the camera, they will be studied on the rectilinear scanner in order to obtain exact localization of the functioning tumor. If an area is found to be equivocal, the study will be repeated in 24 hours after blood background has been reduced.

TITLE OF PROJECT:
The Diagnosis of Functioning Metastasis From Thyroid Carcinoma With I-131 and Scintillation Camera

9. Method of Procedure (continued)

f. On day five after the oral ingestion of I-131, the patient will have a second PBI-131 drawn to ascertain if there has been production of protein bound iodine I-131 by the tumor. Levels of less than 0.004 mg % is indicative of no functioning thyroid tissue or tumor.[2] The "Rezikit" as made by Abbott will be utilized to do the study.

g. Patients who are treated with I-131 for functioning thyroid carcinoma will be studied after the amount remaining in the body is at a safe level (less than 30 mCi retained). Since the therapeutic dose will have extremely high counts, this should give us the best resolution of the lesions. These will be compared with the diagnostic scans.

h. If there is strong suspicion of recurrent metastatic thyroid carcinoma in the neck, the patients will be studied in 3 months. Patients with pulmonary or bone marrow metastasis will be studied at six month intervals. When patients have been found free of disease, they will be studied in 1 to 3 years but return at least once a year for follow-up. If, after the period mentioned above, they are found free of functioning thyroid metastasis, they will be studied at the discretion of the examining physician. Under conditions where I-131 therapy is not working, diagnostic studies of the nature described in the protocol will be discontinued.

APPLICAT..N FOR MEDICAL RESEARCH PROJECT . ..NTINUED)

TITLE OF PROJECT: The Diagnosis of Functioning Metastasis From Thyroid Carcinoma With I-131 and Scintillation Camera

10. REQUIREMENTS (Itemize, with cost, supplies and equipment required and state purpose of any travel requested)

All required equipment is presently available to do the studies listed in the protocol.

FUNDS REQUESTED	
TYPE	AMOUNT
11. EQUIPMENT	$ None
12. SUPPLIES	None
13. TRAVEL	TDY
14. TOTAL	$

15. FUNDS HAVE BEEN RECEIVED OR REQUESTED FROM OTHER SOURCES FOR THIS PROJECT ☐ YES ☒ NO (If yes, specify)

16. ASSISTANCE DESIRED OTHER THAN FINANCIAL ☐ YES ☒ NO (If yes, specify)

17. ADDITIONAL INFORMATION (Use this space and reverse side of form for additional comments)

DOSIMETRY: According to Saenger,[5] an accumulation of 1% of radioiodine 131 in 24 hours will have a whole body radiation dose of 0.14 rads with 1 mCi of radioiodine. According to Pochin, a 150 mCi dose as treatment for functioning thyroid metastasis with a mass of 1.6 grams and a 24 hour uptake of 0.4% will give a tumor dose of 12,000 rads and the whole body dose will be 32 rads.[2] At very low uptake values, as seen in these patients with thyroid carcinoma, most of the whole body dose is due to the inorganic iodine administered. In this patient with 0.4% uptake in 24 hours, the dose due to the inorganic iodine to the whole body is 40 rads with that due the protein bound fraction to radioiodine 131 is 2 rads.[2] This would mean that a patient given a diagnostic dose of 1.5 mCi with an uptake of 0.4% in 1.6 grams of thyroid tissue would have a whole body dose of 0.42 rads.[2] Of course in the event that the uptake is significantly greater and the tissue larger in mass, the protein bound fraction would give more irradiation to the whole body. The estimated biologic half life in the stomach would be about 5 hours.

Because of the proven safety of doses of several millicuries, it would be justifiable to utilize this higher dose in order to determine functioning areas of metastasis.[2,5,6] It would seem prudent to obtain the optimum amount of counting statistics in order to insure that the appropriate treatment will be rendered to the patients.

18. SIGNATURE OF RESPONSIBLE INVESTIGATOR

19. TYPED OR PRINTED NAME, GRADE AND OFFICIAL TITLE OF CHIEF OF SERVICE OR DEPARTMENT, WHERE WORK IS PERFORMED	20. SIGNATURE
Eugene T. Morita, Major, MC Chief, Nuclear Medicine Service	Eugene T. Morita

21. DATE	22. TYPED OR PRINTED NAME OF COMMANDER	23. SIGNATURE

SG FORM 68b
1 JUN 60

REFERENCES:

1 B.Catz, D. Petit, P.Starr, The Diagnostic and Theraputic Value of TSH and Heavy Dose Scintigrams for Demonstration of Thyroid Cancer Metatasis, The American Journal of Medical Science, Vol 237, 1959, P 158-164.

2 E.E. Pochin, Prospects From The Treatment of Thyroid Carcinoma, Clinical Radiology, Vol 18, 1967, P 113-135.

3 G.R. Ridings and W. F. Coffman, Work in Progress; I-131 Retention Curves by Whole Body Counter. Detection of Thyroid Cancer Residual, Radiology, Vol 89, 1967, p 739-740.

4 H.O. Anger, Chapter 19, Radioisotope Camera, P 485-552, Academic Press, Inc., 1967, Edited by G.J. Hine.

5 E.L.Saenger, C.M. Barrett, J.W. Passino, R.A. Seltzer, and W.D Dooley, Experiences With I 131 in the Management of Carcinoma of the Thyroid, Radiology, Vol 83, 1964, P 892-901.

6. I. Hale, T. Reeve and D. Johnson, Management of Functioning Thyroid Carcinoma, Medical Journal of Australia, Vol 1, 1969, P 372-378.

APPLICATION FOR MEDICAL RESEARCH PROJECT
(Army Administrative Letter 70-4)

DATE: 20 April 1970

TO: Commanding General
Headquarters, U. S. Army Medical Research and Development Command
Washington 25, D. C.

FROM:
Nuclear Medicine Service
Fitzsimons General Hospital
Denver, Colorado 80240

TITLE OF PROJECT

Radioactive Iodine-131 Serum Albumin Lumbar-Cisternography and Ventriculography

1. ESTIMATED TIME WORK WILL BEGIN	2. PROBABLE DURATION OF PROJECT
1 July 1970	2 years

3. NAME OF RESPONSIBLE INVESTIGATOR (Append Biography, SG Form 68-1)	4. OFFICIAL POSITION AND TITLE	5. GRADE
Eugene T. Morita	Chief, Nuclear Medicine Service	Maj

6. PROFESSIONAL ASSISTANT(S) (Append Biography(s), SG Form 68-1)

David S. Madison, Maj, MC
Neurology Service

Robert C. Leaver, LTC, MC
Chief, Neurology Service

7. OTHER CURRENT RESEARCH ACTIVITIES OF RESPONSIBLE INVESTIGATOR

None

8. BACKGROUND AND PURPOSE OF STUDY

Introduction and Aims:

DiChiro has refined the technique originally developed by Bauer and Yuhl so as to determine the flow of the cerebral spinal fluid (CSF). It has proved of benefit in the following list:[4]

1. Communicating hydrocephalus
2. Localization of the position of leak in patients with cerebral spinal fluid leaks.
3. Localization of the level and degree of subarachnoid block from spinal cord compression.

Additionally Isotope ventriculography has been used in the following list:[4]

1. Diagnosis of Intraventricular tumors
2. Pre and post-op evaluation of patients with obstructive hydrocephalus
3. Evaluation of the patency of ventricular shunts.

The goal of the project is to offer these studies listed above to the patients at Fitzsimons General Hospital. The purpose is to offer a safe, relatively easy procedure for the diagnosis of the above listed problems.

SG FORM 68
1 JUN 60

16753

APPLICATION FOR MEDICAL RESEARCH PROJECT (CONTINUED)

TITLE OF PROJECT

Radioactive Iodine-131 Serum Albumin Lumbar Cisternography and Ventriculography

9. METHOD OF PROCEDURE (Include observations to be made in each case)

Material and Methods: High specific activity of radioactive iodine-131 albumin (RISA) will be purchased from a licensed radiopharmaceutical company in accordance to our license #05-00046-13. It is routinely tested for pyrogens and sterility. Activity will be about 50 uc per mg of albumin.[2] The patients will be prepared with Lugol's solution. The high specific activity RISA will be diluted in such a way with sterile saline as to be certain that no more than 1 mg of albumin per ml is present.[2] After aseptic preparation of the patient's back, the prepared RISA will be injected into the lumbar or cisternal subarachnoid space. Cisternal injection will be carried out by those who are experienced in the procedure. No more than 100 uc of RISA will be administered per adult.[1,4] Children's dose will be 50 uc.[4] Normally when injected into the lumbar subarachnoid space activity will be noted in the basal cisterns, at 2 hours, 6 hours in the Sylvian cisterns and at 24 hours over the convexities of the brain. By 48 hours the activity will be gone. The patients will be studied with the scintillation camera or on the rectilinear scanner by standard techniques. Appropriate views to best define the pathology will be done at the above intervals.

When the ventricular system is being evaluated, the material will be prepared as previously described and placed in the ventricular system by only those who have had experience in the procedure, the neurosurgeons. Following the injection of the dose the activity will be followed in sequential manner to determine the pathophysiologic circumstances.

When studying patients with leakage of the cerebral spinal fluid (CSF) sterile plugs will be inserted into the nostril and other orifaces of the head to determine where the communication to the external environment has occurred. The material collected in those plugs will be counted in the well counter to determine the content and location of the leak. Appropriate views will be taken in various positions and times which will optimize the evaluation of the CSF leak.

It is estimated that a total of 50 patients will be done. Most patients will be from the inpatient group. The indication for the study have been already listed. All age groups will be studied; if the patient is less than three years of age, the dosage will be calculated on the proportion of the child's weight to the standard adult of 70 kg. Pregnant women will not be studied. Informed consent will be obtained from all patients or a responsible member of the family.

APPLICA[illegible]N FOR MEDICAL RESEARCH PROJECT (CONTINUED)

TITLE OF PROJECT

Radioactive Iodine-131 Serum Albumin Lumbar-Cisternography and Ventriculography

10. REQUIREMENTS *(Itemize, with cost, supplies and equipment required and state purpose of any travel requested)*

Support: The present personnel will perform the studies. The methods for the procedure are the standard methods used in imaging. The studies will be carried out on a rectilinear scanner or a gamma scintillation camera. The cost for the material is about $50.00 for one study.

Significance: The use of radioisotopic methods for studying of the CSF circulation is invaluable and determination of abnormalities has been well documented. The study is quite safe and offers a relatively simple method in the diagnosis of abnormalities in CSF flow.

FUNDS REQUESTED	
TYPE	AMOUNT
11. EQUIPMENT	$ NONE
12. SUPPLIES	NONE
13. TRAVEL	TDY
14. TOTAL	$

15. FUNDS HAVE BEEN RECEIVED OR REQUESTED FROM OTHER SOURCES FOR THIS PROJECT ☐ YES ☒ NO *(If yes, specify)*

16. ASSISTANCE DESIRED OTHER THAN FINANCIAL ☐ YES ☒ NO *(If yes, specify)*

17. ADDITIONAL INFORMATION *(Use this space and reverse side of form for additional comments)*

Dosimetry: When RISA is injected into the lumbar space one-half the activity is gone from this area in two hours.[8] Similar effective half times are found through the spinal cord as the activity moves up.[8] The dose to the cord (target organ) is 6 rads with a 100 uc RISA dose.[6] The timing of the RISA in the cisterns sagittal sinus is mentioned in above and the dose to the brain is 1.3 rads/100 uc of RISA.[4] The biologic half life in the plasma, after absorption in the arachnoid granulations is 7.4 days.[8] After the I-131 has been separated from the albumin, it is excreted by the kidney. The radiation dose to the various organs are as follows:

a. Total body (with blocking agents of perchlorate) 0.17 to 0.3 rads
b. Blood (with blocking doses) 1.56 rads
c. Thyroid (without blocking agents) 100 rads. With blocking agents the rad dose should be that near the blood dose.

The problems with RISA study of the subarachnoid space are related to the high concentration of albumin.[1,2] Concentration of about 1 mg/ml have not been reported to cause problems such as aseptic meningitis. No animal work has been done in animals in this laboratory with respect to RISA. The dose mentioned in the protocol is based on the proven safety and usefulness in the literature.[1,8]

The use of RISA directly into the ventricular system for diagnostic purposes is

18. SIGNATURE OF RESPONSIBLE INVESTIGATOR

19. TYPED OR PRINTED NAME, GRADE AND OFFICIAL TITLE OF CHIEF OF SERVICE OR DEPARTMENT, WHERE WORK IS PERFORMED	20. SIGNATURE
Eugene T. Morita, Maj, MC Chief, Nuclear Medicine Service	Eugene T Morita

21. DATE	22. TYPED OR PRINTED NAME OF COMMANDER	23. SIGNATURE

SG FORM 68b
1 JUN 60

652897

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APPLICATION FOR MEDICAL RESEARCH PROJECT - BIOGRAPHY | DATE: 24 April 197

1. NAME (Last, First, Middle Initial)	2. GRADE	3. AGE	4. SEX	5. BRANCH OF SERVICE	6. MAILING ADDRESS
Madison, David S.	Maj	35	m	Army/MC	Neurology Service Fitzsimons General Hospital Denver, Colorado 80240

EDUCATION - COLLEGE AND/OR UNIVERSITY

NAME AND LOCATION OF INSTITUTION	MAJOR OR COURSE	DATES FROM	DATES TO
7. See attached information			
8.			
9.			
10.			

RESEARCH TRAINING

NAME AND LOCATION OF INSTITUTION	SUBJECT	RESEARCH DIRECTOR	DATES FROM	DATES TO
11. See attached information				
12.				
13.				
14.				

15. OTHER QUALIFICATIONS *(Hospital Appointments, Professional Societies, Specialty Board, etc)* *(IF MORE SPACE IS NEEDED CONTINUE ON REVERSE SIDE)*

See attached information

BIBLIOGRAPHY *(Do Not List More Than Ten Publications)*

16. See attached information

17.

18.

19.

20.

21.

22.

23.

24.

25.

SG FORM 68-1
1 JUN 60

Title of Project:
Radioactive Iodine-131 Serum Albumin Lumbar-Cisternography and Ventriculography

17. (Additional Information continued)

9. R. A. Seltzer, J. G. Kergiakes, E. L. Saenger and D. H. Meyers: "Radiation Exposure from Radioiodine Compounds in Pediatrics Radiology," Vol 82, p 486-494, 1964

10. J. G. McAfee, C. F. Fueger, H. S. Stern, H. N. Wagner Jr. and T. Migita: "Journal of Nuclear Medicine," Vol 5, p 811-827, 1964

11. E. M. Smith: "Internal Dose Calculation for Technetium-99m," Journal of Nuclear Medicine, Vol 6, p 231-251, 1965

Title of Project:
Radioactive Iodine-131 Serum Albumin Lumbar-Cisternography and Ventriculography

17. (Additional Information continued)

generally followed with corrective edures such as placement of a ventricular shunt to relieve obstruction. The blood doses will be related to the RISA present in the plasma and has already been described.

Other procedures such as brain scan may be done in these patients with a Tc 99 Pertechnetate. The dose is 10 mc in adults and scaled down accordingly for children. The dose to the organs will be as follows (with a blocking agent):

a. Upper large bowel 0.96 rads (critical organ)
b. Gonads 0.12 to 0.15 rads
c. Stomach 0.59 rads
d. Thyroid 0.09 rads
e. Total body 0.12 rads
f. Blood 0.12 rads

Fitzsimons General Hospital is a large referral center of approximately 1150 beds and numerous difficult diagnostic problems are referred to this clinic. The qualifications of the primary investigator are listed in the curriculum vitae and the isotope experience is also listed.

Annual reports will be forwarded to the Atomic Energy Commission through the Surgeon General's Office and also the Clinical Research Section.

REFERENCES:

1. C. H. Tator, J. F. Fleming, R. H. Sheppard, and V. M. Turner: "A Radioisotopic Test for Communicating Hydrocephalus," Journal of Neurosurgery, Vol 28, #4, p 327-340,

2. W. L. Ashburn, J. C. Harbert, W. H. Briner and G. DiChiro: "CSF Rhiorrhea Studied with the Gamma Scintillation Camera," Journal of Nuclear Medicine, Oct 1968, Vol 9, #9 p 523-529

3. J. P. Williams, R. H. Lynde, and A. R. Sharpe: Isotope Cisternography, Scientific Exhibit presented at the National Meeting of the Society of Nuclear Medicine in New Orleans, La., Jul 1969

4. C. D. Maynard: "Clinical Nuclear Medicine, Chapter 7, Nervous System, p 158-194

5. C. F. Nicol: "A Second Case of Aseptic Meningitis Following Isotope Cisternography Using I-131 Human Serum Albumin," Neurology 17, p 199-200, 1967

6. G. DiChiro: "Personal Communication," March 1970

7. G. DeNardo: "Personal Communication," July 1969

8. S. N. Chou and L. A. French: "Neurology #5," 1955, P 555-557

David S. Madison, Maj, MC

Undergraduate education was completed at University of Colorado in Boulder 1952-1957

Medical School was the University of Colorado Medical School in Denver, 1957-1961

Internship was at William Beaumont AH, El Paso, Texas, from July 1961 to July 1962

Residency (Neurology) was at Walter Reed AH, Washington, D. C., from 1962-1965

Fellowship Electroencephalography, John Hopkins Hospital, Baltimore, Md. from August 1968 to January 1969

Publications:

"Seizures due to Acute Cerebral Anoxia." E. Neidermyer, accepted by Journal of Neurology and Neurosurgery and Psychiatry

SUBMIT IN DUPLICATE

APPLICATION FOR MEDICAL RESEARCH PROJECT

(OTSG Administrative Letter 70-4)

DATE: 20 April 1970

TO: Commanding General
Headquarters, U. S. Army Medical Research and Development Command
Washington 25, D. C.

FROM:
Nuclear Medicine Service
Fitzsimons General Hospital
Denver, Colorado 80240

TITLE OF PROJECT

Joint Imaging with Technetium-99m Pertechnetate

1. ESTIMATED TIME WORK WILL BEGIN	2. PROBABLE DURATION OF PROJECT
1 July 1970	2 years

3. NAME OF RESPONSIBLE INVESTIGATOR (Append Biography, SG Form 68-1)	4. OFFICIAL POSITION AND TITLE	5. GRADE
Eugene T. Morita	Chief, Nuclear Medicine Service	Maj, MC

6. PROFESSIONAL ASSISTANT(S) (Append Biography(s), SG Form 68-1)

Robert Smith, Maj, MC, Rheumatology Clinic

7. OTHER CURRENT RESEARCH ACTIVITIES OF RESPONSIBLE INVESTIGATOR

None

8. BACKGROUND AND PURPOSE OF STUDY

Introduction and Specific Aims: Joint scanning has been utilized in various disorders of joints in order to determine the degree of inflammation and has been recently used to determine the progress of an inflammatory process in the joints. It is particularly useful in the military medicine in determining if a joint complaint is real or imagined. Sholkoff and Glickman have shown that the scan has been positive when the physical examination and x-rays have been negative.[1] Their findings were borne out later when clinically apparent disease developed in the positive area seen in joint scanning. The purpose of this study is to determine its usefulness in patients with various disorders of joints and to see if it is useful in evaluating the course of the disease and its relationship of treatment.

16753

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1 JUN 68

APPLIC. ON FOR MEDICAL RESEARCH PROJEC .CONTINUED)

TITLE OF PROJECT

Joint Imaging with Technetium 99m Pertechnetate

9. METHOD OF PROCEDURE (Include observations to be made in each case)

Approximately 100 patients will be studied on the scintillation camera. The normals will be obtained from those patients without joint complaints who are having brain scans. History will be obtained from these normal patients with respect to their joint symptoms and examination of the joints will be made during scanning. Only patients giving informed consent will be utilized for obtaining the normals. The hands, wrists, elbows, shoulders, neck, hips, knees, ankles and feet will be studied in normals. Approximately 20 normals will be obtained.

In patients with joint complaints, the joint involved and the contralateral joint will be scanned. If the clinical history dictates a certain type of arthritis, specific joints will be studied. For example, patients with rheumatoid arthritis will always have their wrist and hands scanned. All age groups will be studied. Pregnant patient will not be studied. The dosage used will be 3 mCi per patient of T3-99m Pertechnetat Dose for children will be calculated on the basis of the child's weight in kg over 70 kg. The material will be purchased and handled in accordance with our license #05-00046-13. The patients will be given 500 mg of potassium perchlorate in order to block uptake of the Tc-99m into the thyroid. Thirty minutes will elapse before they are scanned.

The 4,000 hole low energy colluminator will be used for the study. Approximately 30,000 to 40,000 will be obtained of every joint in question and the time required to obtain these counts will be used to study the other joints so as to give a quantitative information. As the study progresses, qualitative scores will be given from four plus to normal. This will be made on the basis of counts per unit of time. The purpose of such a scoring system is to determine if the scan can be used in determining the efficiency of treatment. Similar positioning of the joint will be made in order to remove the factor of varying positions in the joint scan.

The accompanying form will be used in evaluating the usefulness of joint scanning. The forms will be kept in the Nuclear Medicine file and the scans will be color coded and a list of all joint scans will be kept in a separate book.

PATIENT: AGE: FROM:

DIAGNOSIS:

DATES	PE	XRAY	SCAN	LAB

APPLICATION FOR MEDICAL RESEARCH PROJECT (CONTINUED)

TITLE OF PROJECT

Joint Imaging with Technetium-99m Pertechnetate

10. REQUIREMENTS *(Itemize, with cost, supplies and equipment required and state purpose of any travel requested)*

Facilities: The scintillation camera will be used. Personnel are presently available who are familiar with its use. Our present Mo99 cow is more than sufficient to obtain Tc-99. No additional cost referable to materials is expected.
Report will be submitted annually. These will go to the SGO with respect to AEC requirements and to the Clinical Research Section.

Significance: The purpose of joint scanning is to offer the physician another modality in evaluating patients with joint symptoms. It is hoped that qualitative information can be obtained so as to be used in evaluating the course of an arthritis and also to determine the efficacy of treatment.

FUNDS REQUESTED	
TYPE	AMOUNT
11. EQUIPMENT	$ None
12. SUPPLIES	None
13. TRAVEL	TDY
14. TOTAL	$

15. FUNDS HAVE BEEN RECEIVED OR REQUESTED FROM OTHER SOURCES FOR THIS PROJECT ☐ YES ☒ NO *(If yes, specify)*

16. ASSISTANCE DESIRED OTHER THAN FINANCIAL ☐ YES ☒ NO *(If yes, specify)*

17. ADDITIONAL INFORMATION *(Use this space and reverse side of form for additional comments)*

Dosimetry: Tc-99m is a safe radionuclide. The target organ is the upper large intestines. The dose to the upper large bowel is 0.12 rads with 3 mCi of Tc-99m Pertechnetate. With Tc-99m the biologic half life is broken into two components; the first being 10 minutes and the slower component 6 hours. About 90% of the administered dose is excreted in 24 hours via the kidneys. Of the remaining dose 90% is excreted in the stool in the second and third day. The biologic half life in the stomach is 6 hours and the remaining dose is decreased by 50% with the administration of potassium perchlorate. The other organ doses with blocking drug with 3 mCi Tc-99m are as follows

a. Blood - 0.45 rads
b. Total body - 0.45 rads
c. Gonads - 0.4 - 0.5 rads
d. Thyroid - 0.03 rads

The work with Tc-99m Pertechnetate has shown it to be extremely useful and safe isotope Its safety has been shown by its use in brain imaging. No concurrent radionuclide administration is contemplated.

Fitzsimons General Hospital is a large referral center of approximately 1150 beds and

18. SIGNATURE OF RESPONSIBLE INVESTIGATOR

19. TYPED OR PRINTED NAME, GRADE AND OFFICIAL TITLE OF CHIEF OF SERVICE OR DEPARTMENT, WHERE WORK IS PERFORMED	20. SIGNATURE
EUGENE T. MORITA, MAJ, MC Chief, Nuclear Medicine Service	Eugene T. Morita

21. DATE	22. TYPED OR PRINTED NAME OF COMMANDER	23. SIGNATURE
20 Apr 70		

SG FORM 68b
1 JUN 60

65 2997

TITLE OF PROJECT:
Joint Imaging with Technetium-99m Pertechnetate

17. (Additional Information continued)

numerous difficult problems are referred here for diagnostic evaluation and treatment. The qualification of the primary investigator are listed in the curriculum vitae and the isotope experience is also listed.

Annual reports will be forwarded to the Atomic Energy Commission through the Surgeon General's Office and also to the Clinical Research Section.

REFERENCES:

1. Sholkoff, S. D. and Glickman, M. G.: "Scintiphotographic Evaluation of Arthritis Activity," Investigative Radiology, Vol 4, July-August 1969, p 207-214

2. Weiss, T. E., Maxfield, W. S., Murison, P. J., Hidalgo, J. U.: "Scinti[illegible]ation Scanning in Rheumatoid Arthritis," Southern Medical Journal, Vol 59, #4, April 1966, p 484-488

3. Smith, E. M.: "Internal Dose Calculation for Technetium 99m," Journal of Nuclear Medicine, Vol 6, p 231-251, 1965

4. McAfee, J. G., Fueger, C. F., Stern, H. S., Wagner, H. N. Jr., and Migita, T: "Tc-99m Pertechnetate for Brain Scanning," Journal of Nuclear Medicine, Vol 5, p 811-8[illegible] 1964

APPLICATION FOR MEDICAL RESEARCH PROJECT - RESEARCH | 30 Mar 70

1. NAME (Last, First, Middle Initial)	6. MAILING ADDRESS
Morita, Eugene T	Nuclear Medicine Service Fitzsimons General Hospital Denver, Colorado 80240

2. GRADE	3. AGE	4. SEX	5. BRANCH OF SERVICE
Maj	34	Male	Army

EDUCATION - COLLEGE AND/OR UNIVERSITY

NAME AND LOCATION OF INSTITUTION	MAJOR OR COURSE	DATES FROM	DATES TO
7. Ursinus College, Collegeville, Pa	Chemistry Major	1954	195
8. Jefferson Medical College, Philadelphia, Pa	Medicine	1958	196
9. Presbyterian Hosp, Philadelphia, Pa	Internship	1962	196
10. Letterman General Hospital, Presidio of San Francisco, Calif	Internal Medicine Residency Nuclear Medicine Fellowship	Sep 65	Sep 6

RESEARCH TRAINING

NAME AND LOCATION OF INSTITUTION	SUBJECT	RESEARCH DIRECTOR	DATES FROM	DATES TO
11.				
12.				
13.				
14.				

15. OTHER QUALIFICATIONS (Hospital Appointments, Professional Societies, Specialty Board, etc) (IF MORE SPACE IS NEEDED CONTINUE ON REVERSE SIDE)

Awards: Certificate of Merit, AMA Exhibit on Melioidosis, Section of Internal Medici Scientific Exhibit, San Francisco, 1968

Gold Award, Scientific Exhibit, American Society of Clinical Pathology and The College of American Pathologist, Educational Class-Melioidosis, A Wide Spectrum o Disease, 1968

Organizations: Society of Nuclear Medicine, Asst. Prof. of P Biology, Colo.Gen. Hosp. American Medical Association

BIBLIOGRAPHY (Do Not List More Than Ten Publications)

16. Systemic Melioidosis Presenting as Myocardial Infarct, Annuals of Internal Medicine, Vol 67, #4, Oct 1967, p 836-842, Billy B. Baumann and Eugene T Morita.

17. Isotope Studies in Pulmonary Embolism and Bronchoconstriction, Current Concepts of Internal Medicine, Letterman General Hospital, Vol II, June 1969, p 36-43

18. Artefacts on Liver Scanning to be published, Surgical Oncology

19. Liver Scanning - A Useful Diagnostic Tool, Current Concepts of Internal Medicine, Letterman General Hospital, August 1969, Vol II, p 385-393

20.

21.

22.

23.

24.

25.

APPLICATION FOR MEDICAL RESEARCH PROJECT - BIOGRAPHY

DATE: 24 Apr 70

1. NAME (Last, First, Middle Initial)	2. GRADE	3. AGE	4. SEX	5. BRANCH OF SERVICE	6. MAILING ADDRESS
Smith, Robert W , III	Maj	33	M	USA/MC	Dept of Medicine, Rheumatology Fitzsimons General Hospital Denver, Colorado 80240

EDUCATION - COLLEGE AND/OR UNIVERSITY

NAME AND LOCATION OF INSTITUTION	MAJOR OR COURSE	DATES FROM	DATES TO
7. Georgia Tech, Atlanta, Ga	Chemical Engineer	1954	1956
8. Emory University, Atlanta, Ga	Chemistry	1957	1958
9. University of Tenn, Med School,Memphis,Tenn	Medicine	1960	1963
10. Talmadge Mem Hosp, Augusta, Ga	Internship	1963	1964

RESEARCH TRAINING

NAME AND LOCATION OF INSTITUTION	SUBJECT	RESEARCH DIRECTOR	DATES FROM	DATES TO
11. Medical College, Ga Hosp, Augusta, Ga	Rheumatology	Joseph P. Bailey Jr.	1967	1968
12.				
13.				
14.				

15. OTHER QUALIFICATIONS *(Hospital Appointments, Professional Societies, Specialty Board, etc) (IF MORE SPACE IS NEEDED CONTINUE ON REVERSE SIDE)*

1. Attending physician - medicine- Forrest Hills VAH, Augusta, Ga - 1968
2. Chief Resident Medicine - Medical College, Georgia, 1966-1967
3. Member, American Rheumatism Association

BIBLIOGRAPHY *(Do Not List More Than Ten Publications)*

16. None
17.
18.
19.
20.
21.
22.
23.
24.
25.

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Form HQ 372
(Rev.)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Fitzsimons General Hospital

Address:

City: Denver State: Colorado

2. Control No. (16753) JEB

3. Department Nuclear Medicine Service

4. Name and title of trained individual

Eugene T. Morita, M.D.

5. Type program:

- [ ] Private practice.
- [ ] Private practice in hospital.
- [x] Institutional.

6. Review

- [x] First.
- [ ] Second.

7. Previous application control No.(s)

8. Remark on checked items:

- [ ] A. All radioisotopes and uses stated in application.
- [x] B. Use of (a) I-131 for diagnosis of functioning metastasis from thyroid carcinoma.
- [ ] C. Training and experience of user.
- [ ] D. Dosage(s) indicated.
- [ ] E. Clinical techniques and procedures outlined.
- [ ] F. Type patient used (i.e., terminal, infants, normal).
- [ ] G. Other

(b) I-131 for cisternography and ventriculograph
(c) Tc 99m for joint Imaging

REVIEW: All members

9. Action of Subcommittee on Human Applications:

- [ ] Approve.
- [ ] Disapprove.

Remarks:

(a) Dissapprove. I am apposed to rendering patients athyreotic in order to do these studies, especially those without evidence of metastases. The resultant increase in TSH could activate quiescent disease.

(b) Approve.

(c) Approve. I do not believe this approach will be clinically useful but I can see no harm in their trying.

Original Signed by
G. B. WEST, M.D.

8/12/70
(Date of appraisal)

Signature

(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 747-515

Form HQ 272
(10-64)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Fitzsimons General Hospital

Address:

City: Denver State: Colorado

2. Control No. (16753) JEB

3. Department Nuclear Medicine Service

4. Name and title of trained individual

Eugene T. Morita, M.D.

5. Type program:

- [ ] Private practice.
- [ ] Private practice in hospital.
- [x] Institutional.

6. Review

- [x] First.
- [ ] Second.

7. Previous application control No.(s)

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- [ ] E. Clinical techniques and procedures outlined.
- [ ] F. Type patient used (i.e., terminal, infants, normal).
- [ ] G. Other

(b) I-131 for cisternography and ventriculograp
(c) Tc 99m for joint Imaging

REVIEW: All members

9. Action of Subcommittee on Human Applications:

- [x] ~~A~~pprove.
- [ ] Disapprove.

Remarks:
(a)

(b)

(c)

Aug 8, 1970
(Date of appraisal)

Signature Robert J. Habel
(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 747-315

Form HQ 272
(Rev. 4)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Fitzsimons General Hospital

Address:

City: Denver State: Colorado

2. Control No. (16753) JEB

3. Department Nuclear Medicine Service

4. Name and title of trained individual

Eugene T. Morita, M.D.

5. Type program:

- [ ] Private practice.
- [ ] Private practice in hospital.
- [x] Institutional.

6. Review

- [x] First.
- [ ] Second.

7. Previous application control No.(s)

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- [ ] F. Type patient used (i.e., terminal, infants, normal).
- [ ] G. Other

(b) I-131 for cisternography and ventriculography
(c) Tc 99m for joint Imaging

REVIEW: All members

9. Action of Subcommittee on Human Applications:

- [x] Approve.
- [ ] Disapprove.

Remarks:

(a) Approve

(b) approve

(c) approve

8-7-70
(Date of appraisal)

Signature (Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1968 241-515

Form AEC 272
(10-64)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Fitzsimons General Hospital

Address:

City: Denver State: Colorado

2. Control No. (16753) JEB

3. Department Nuclear Medicine Service

4. Name and title of trained individual

Eugene T. Morita, M.D.

5. Type program:

☐ Private practice.

☐ Private practice in hospital.

☒ Institutional.

6. Review

☒ First. ☐ Second.

7. Previous application control No.(s)

8. Remark on checked items:

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☐ C. Training and experience of user.

(b) I-131 for cisternography and ventriculograph
(c) Tc 99m for joint Imaging

☐ D. Dosage(s) indicated.

REVIEW: All members

☐ E. Clinical techniques and procedures outlined.

☐ F. Type patient used (i.e., terminal, infants, normal).

☐ G. Other

9. Action of Subcommittee on Human Applications:

☒ Approve. ☐ Disapprove.

Remarks:

(a) Approve

(b) approve

(c) approve -

8/5/70
(Date of appraisal)

Signature Henry W. Wagner ?
(Member of subcommittee)

☆ U.S. GOVERNMENT PRINTING OFFICE: 1964 741-515

Form AEC 372
(10-64)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Fitzsimons General Hospital

Address:

City: Denver State: Colorado

2. Control No. (16753) JEB

3. Department Nuclear Medicine Service

4. Name and title of trained individual

Eugene T. Morita, M.D.

5. Type program:

- [ ] Private practice.
- [ ] Private practice in hospital.
- [x] Institutional.

6. Review

- [x] First.
- [ ] Second.

7. Previous application control No.(s)

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- [ ] E. Clinical techniques and procedures outlined.
- [ ] F. Type patient used (i.e., terminal, infants, normal).
- [ ] G. Other

(b) I-131 for cisternography and ventriculograph
(c) Tc 99m for joint Imaging

REVIEW: All members

9. Action of Subcommittee on Human Applications:

- [x] Approve.
- [ ] Disapprove.

Remarks:
(a)

(b)

(c)

7/28/70
(Date of appraisal)

Signature John E. Christian (Member of subcommittee) Ph.D.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 747-515

Form HQ 322
(10-68)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Fitzsimons General Hospital

Address:

City: Denver State: Colorado

2. Control No. (16753) JEB

3. Department Nuclear Medicine Service

4. Name and title of trained individual

Eugene T. Morita, M.D.

5. Type program:

☐ Private practice.

☐ Private practice in hospital.

☒ Institutional.

6. Review

☒ First. ☐ Second.

7. Previous application control No.(s)

8. Remark on checked items:

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☐ C. Training and experience of user.

(b) I-131 for cisternography and ventriculograph
(c) Tc 99m for joint Imaging

☐ D. Dosage(s) indicated.

REVIEW: All members

☐ E. Clinical techniques and procedures outlined.

☐ F. Type patient used (i.e., terminal, infants, normal).

☐ G. Other

9. Action of Subcommittee on Human Applications:

☒ Approve. ☐ Disapprove.

Remarks:
(a)

(b)

(c)

7/23/70
(Date of appraisal)

Signature Daniel C. Kelly M.D.
(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1968 — 747-315

Form HQ 272
(10-64)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Fitzsimons General Hospital

Address:

City: Denver State: Colorado

2. Control No. (16753) JEB

3. Department Nuclear Medicine Service

4. Name and title of trained individual

Eugene T. Morita, M.D.

5. Type program:

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6. Review

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☐ D. Dosage(s) indicated.

REVIEW: All members

☐ E. Clinical techniques and procedures outlined.

☐ F. Type patient used (i.e., terminal, infants, normal).

☐ G. Other

9. Action of Subcommittee on Human Applications:

☒ Approve. ☐ Disapprove.

Remarks:
(a)

(b)

(c)

7 21 '70
(Date of appraisal)

Signature *James L. Quinn, III*
(Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 747-315

Form AEC 272
(10-64)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

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3. Department Nuclear Medicine Service

4. Name and title of trained individual

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5. Type program:

[ ] Private practice.

[ ] Private practice in hospital.

[X] Institutional.

6. Review

[X] First. [ ] Second.

7. Previous application control No.(s)

8. Remark on checked items:

[ ] A. All radioisotopes and uses stated in application.

[X] B. Use of (a) I-131 for diagnosis of functioning metastasis from thyroid carcinoma.

[ ] C. Training and experience of user.

[ ] D. Dosage(s) indicated.

[ ] E. Clinical techniques and procedures outlined.

[ ] F. Type patient used (i.e., terminal, infants, normal).

[ ] G. Other

(b) I-131 for cisternography and ventriculograph
(c) Tc 99m for joint Imaging

REVIEW: All members

9. Action of Subcommittee on Human Applications:

[ ] Approve. [ ] Disapprove.

Remarks:

(a) approve

(b) approve

(c) disapprove. What will this accomplish besides perhaps identifying malingerers?

(Date of appraisal) 7/20/70

Signature (Member) Harold H. Rossi

H.H. Rossi

Form HQ 272
(10-64)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Fitzsimons General Hospital

Address:

City: Denver State: Colorado

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(c) Tc 99m for joint Imaging

REVIEW: All members

☐ D. Dosage(s) indicated.

☐ E. Clinical techniques and procedures outlined.

☐ F. Type patient used (i.e., terminal, infants, normal).

☐ G. Other

9. Action of Subcommittee on Human Applications:

☐ Approve. ☐ Disapprove.

Remarks:
(a)

(b)

(c)

(Date of appraisal) Signature (Member of subcommittee)

☆ U. S. GOVERNMENT PRINTING OFFICE: 1964 — 747-315