

*(Refusal) of*  
*11 August 1955*

ARM1.950103.014

Chief, Medical Plans and Operations Div., OTSG

11 August 1955

Legal Office

## Permit for Radioisotope Therapy

1. Reference is made to the attached correspondence and memoranda, subject as above.
2. It is suggested that this information be processed either as a change to AR 40-200 or published as an administrative letter or other media for information to Class II and III hospitals.

Incls  
a/sDAVID E. MARCHUS  
Major, MSC  
Chief, Legal Office*UNRC : 30 Dec 94 Archives**RG : 112**Accession # 69A-127**Box # 8**File Name : 401-02 Medical Treatment Consent  
to Refusal DF, 1944-65*

RECEIVED

MEDDD-HO  
NO. 2

DATE: 5 August 1955  
Capt Holbrook/62840/mf

TO: Chief, Legal Office  
Chief, Medical Statistics Division  
IN TURN

FROM: Chief, Medical Plans and Operations Division

This division concurs in the above-comments of the Medical Statistics Division.

1 Incl  
n/c

THOMAS N. PAGE  
Colonel, M. C.

Chief, Medical Plans and Operations Division  
 Chief, Legal Office  
IN TURN

3 August 1955

Chief, Medical Statistics Division

Permit for Radioisotope Therapy

1. Reference is made to attached letter from Colonel Wells, Chief, Radiological Service, Letterman Army Hospital, concerning the desirability of obtaining an authorization for radioisotope therapy from the patient concerned; to memorandum, Chief, Medical Plans and Operations Division to Chief, Legal Office, 8 April 1955, subject as above; and to memorandum, Chief Legal Office to this division, 20 July 1955, subject as above.

2. It is the opinion of this division that Standard Form 522, Clinical Record—Authorization for Administration of Anesthesia and Performance of Operations and Other Procedures, is adequate for use in those instances when authorization for administration of radioisotope therapy is desired. It is suggested that signature by a patient of an authorization form which lists possible side effects or undesired results of such therapy may not relieve a hospital or physician of professional or legal responsibility. This division agrees with the view expressed by Medical Plans and Operations Division that the development of a special authorization form for one procedure may imply a requirement for such forms for other procedures, such as the administration of nitrogen mustard, of which issue and use is also controlled under SR 52-10-10.

Incl n/c

EUGENE L. HAMILTON

*Legal Office*

3 134  
1955  
MEDCL

Chief, Medical Statistics Division, OTSG

20 July 1955

Legal Office

Permit for Radioisotope Therapy

1. Reference is made to paragraph 4 of the attached memorandum from the Chief, Medical Plans and Operations Division.
2. It is requested that you take whatever action you deem necessary in order to solve the problem presented.

1 Incl.  
n/c

DAVID E. MARCHUS  
Major, MSC  
Chief, Legal Office

RECEIVED  
 APR 11 1955  
 MEDDD-EO  
 NO. 2

Chief, Legal Office

8 April 1955  
 Capt Hammond/mf/62840

Chief, Medical Plans and Operations Division

Permit for Radioisotope Therapy

1. In accordance with paragraph 2, Memorandum Number 1, this subject was discussed by The Coordinating Committee on Organizational and Procedural Problems Connected with Care of Mass Casualties and Atomic Medicine, on 29 March 1955.

2. The policy prescribed in paragraph 4a, AR 40-610, is considered adequate in the matter of requiring patients to sign a permit for radioisotope therapy. These regulations require that except in an emergency, written consent for the performance of therapeutic and diagnostic procedures on civilian patients will be obtained in accordance with the usual procedures and policies followed by civilian medical and dental practitioners. There is no such requirement in the case of military patients, nor is such a requirement considered desirable.

3. Many potentially dangerous substances and substances which may have undesirable side reactions are currently being administered without any requirement for written consent of the patients. It is believed unwise to establish a precedent in the case of radioisotopes, which might later be extended to a large number of other medications. In some instances, the authorization statement which the patient is required to sign might serve only to create undue alarm. In these instances, the physician should be free to exercise his professional judgment in determining whether written consent of the patient should be required.

4. For those cases where an "Authorization for Administration of Radioactive Materials" is determined by the physician to be indicated, it was agreed that a standard form, to be signed by the patient and become a part of the Clinical Record, should be adopted. It is recommended that copies of this correspondence be furnished to the Chief, Medical Statistics Division for preparation of the necessary form or appropriate comments on the utilization of existing standard forms to accomplish this purpose.

1 Incl  
 n/c

C. F. ST. JOHN  
 Colonel, M. C.

STANDARD FORM NO. 64

*Office Memorandum* • UNITED STATES GOVERNMENT

TO : Medical Plans &amp; Operations Division, OTSG

DATE: 2 February 1955

FROM : Legal Office, OTSG

SUBJECT: Permit for Radioisotope Therapy

1. Your attention is invited to the attached letter addressed to Colonel Lodmell from Colonel Wells.

2. I believe that the problem stated in this letter is of sufficient importance that an Army Medical Service-wide policy should be established.

3. It is therefore recommended that representatives of your office, Professional Division, and the Legal Office meet with the view of determining what The Surgeon General's policy in this matter should be.

1 Incl  
ltr dtd 14 Jan 55

DAVID E. MARCHUS  
Major, MSC  
Chief, Legal Office



Dr. Miller and I am enclosing a copy of the letter  
with your signature on which impresses me as a quite anonymous  
writing. I believe could be improved upon. I am told  
that a form is required at Stanford by Dr. Newell but he is out  
and I can get no information.

It would also like to know if you approve of the authorization used  
at the Good Hospital for radiophosphorus and also radio iodine in  
the treatment of thyroid cancer, copies of which I am enclosing.

Any information you can give me along these lines will be greatly  
appreciated.

Sincerely,

PAUL O. KELLS  
Colonel, M.C.  
Chief, Radiological Service

FROM

Dr. Earl Miller  
Univ. of Calif. Med Center  
Radioiodine Laboratory

INFORMATION FOR PATIENTS RECEIVING RADIOIODINE

In order to study how your thyroid gland (goiter) is acting, we need to give you a small amount of radiiodine.

Radiiodine gives off radiations called beta rays and gamma rays. These rays are like x-rays and too many of them are harmful but thousands of people are examined by means of x-rays every day with no harmful effects. To the best of our knowledge, the amount of radiation you will receive will do you no harm.

We want you to understand that you are receiving small quantities of radiation after you drink the solution of radiiodine and ask you to sign that you have read and understand this brief statement.

DO NOT SIGN THIS IF YOU ARE PREGNANT.

Signature \_\_\_\_\_

Date \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

INFORMATION FOR PATIENTS RECEIVING RADIO-IODINE

In order to treat the disease of your thyroid gland, we want to give you radio-iodine. Radio-iodine gives off beta and gamma rays while in your body - mostly in the thyroid gland. Beta and gamma rays act on the body much like x-rays. X-rays have been used for treatment of certain thyroid diseases for many years. While the use of radio-iodine is still experimental, we believe it will be more satisfactory than x-rays.

We want you to know that you are receiving radio-iodine when you drink the solution given you and to show that you have read and understood this simple statement please sign below.

Signature.....

Date.....

.....

..... MO

~~MEDICAL RECORD~~

AUTHORIZATION FOR ADMINISTRATION OF ANESTHETIC

1. I hereby consent to the performance upon:

(Diagnostic and/or therapeutic procedure to be performed)

(Signature of patient)

When patient is unable to affix signature or is legally incompetent:

affirmed by:

(Signature of consenting person)

(Relationship to patient)

(Signature of witness)

(Address)

(City & State)

(Date)

Patient's Name (Last, First & Middle Name)

Register No. Ward

Name of Hospital or Other Medical Facility

... (131) Iodine with Suggested Conditions. As a guide  
 to the physician for administration of radioactive material  
 for the purpose of further clarification.

1. Radioactive Iodine ( $^{131}\text{I}$ ) for treatment of hyperthyroidism:

The expected beneficial results and the possible undesirable results  
 (the latter including such real possibilities as sore throat and  
 hypothyroidism and such speculative possibilities as malignant change)  
 of this form of treatment have been explained to me to my satisfaction.

2. Phosphorus ( $^{32}\text{P}$ ) for treatment of leukemia or polycythemia vera:

The expected beneficial results and the possible undesirable results  
 (the latter including radiation sickness and depression of the pro-  
 forming functions of the bone marrow) of this form of treatment  
 have been explained to me to my satisfaction.

3. Radioiodine ( $^{131}\text{I}$ ) for inducing hypothyroidism in euthyroid patients  
 with pre-existing angina pectoris and/or chronic congestive heart failure:

The expected beneficial results and the possible undesirable results  
 (the latter including such a real possibility as sore throat and  
 speculative possibilities as sterility and malignant change) of  
 this form of treatment have been explained to me to my satisfaction.

I understand that this treatment is for the purpose of destroying  
 thyroid tissue, normal as well as diseased; and that a permanent  
 replacement therapy in the form of thyroid medication must be  
 given if a normal metabolic state is to be maintained.

(111) for treatment of thyroid cancer:

The expected beneficial results and the possible undesirable results (the latter including such a real possibility as sore throat and such speculative possibilities as sterility and malignant changes) of this form of treatment have been explained to me to my satisfaction. Also, I understand that this treatment is for the purpose of destroying all thyroid tissue, normal as well as diseased; and, that a permanent need for replacement therapy in the form of thyroid medication must be expected if a normal metabolic state is to be maintained.

5. Radiogold (Au<sup>198</sup>) for intracavitary instillation in the treatment of effusions due to malignancies;

The expected beneficial results and the possible undesirable results (the latter including radiation sickness and depression of the blood-forming functions of the bone marrow) of this form of treatment have been explained to me to my satisfaction.

6. Any diagnostic study involving the use of radiomaterial:

The nature of the procedure to be performed and the meaning of the word "radioactive" have been explained to me to my satisfaction.