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application

LR:IB:BWC (50605)

University of Tennessee
College of Medicine
62 S. Dunlap
Memphis 3, Tennessee

Attention: John Q. Adams, M.D.

Gentlemen:

This is in response to your application dated April 4, 1963, for byproduct material license and supporting letters dated June 6, 1963, and July 25, 1963.

The use of byproduct material for studies in pregnant patients is considered non-routine and experimental and, accordingly, demands a high degree of justification with respect to the clinical benefits derived for the management of abnormal pregnant patients. Your request for the continued use of Iodine 131 as Iodinated Human Serum Albumin for the study of cardiovascular hemodynamics and hemorrhagic shock in normal and abnormal obstetrical patients has been carefully reviewed by the Commission with the assistance of the Commission's Advisory Committee on the Medical Use of Isotopes. The Advisory Committee feels that such studies do not justify the continued use of byproduct material in pregnant patients on the basis of the information you have submitted.

Accordingly, you are requested to supplement your application with the following information:

1. A complete research protocol including an exact and definitive statement of the proposed studies with respect to the types of patients to be studied, the doses administered, the methods to be used, and the specific results which you hope to obtain from each patient.

2. A detailed description of your previous experimentation with ten normal and ten abnormal pregnant patients including data obtained from each patient and justification for the continued use of

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Iodine 131 in normal pregnant controls. You should also explain any differences between these studies and the proposed studies.

3. A justification for the use of pregnant human subjects rather than animals or non-pregnant patients to compare T-1824 and RISA in vivo behavior.

Sincerely yours,

Cecil R. Buchanan
Assistant Chief, Isotopes Branch
Division of Licensing and
Regulation

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SCHOOL OF MEDICINE
NASHVILLE 5, TENNESSEE

January 31, 1958

OFFICE OF THE DEAN

Mr. Cecil E. Eschenbach, Assistant Chief
Isotope Extension
Division of Licensing and Regulation
United States Atomic Energy Commission
Oak Ridge, Tennessee

Dear Mr. Eschenbach:

RE: Your letter of January 27, 1958
(LEB:JEB (8-56).

The dosage of I^{131} as the iodide to be used in treating patients with heart and lung disease averages 20 mc. per month for three months, a total dose of 60 mc. The range is 40-60 mc. Patients with intractable angina and congestive heart failure are candidates for such management. The type of lung condition to be treated in this manner is chronic pulmonary disease such as pulmonary emphysema with severe respiratory insufficiency. Tritium (H^3) will be used to determine total body water. Carbon^{14} in the form of $BaCO_3$ and sodium acetate and the amino acids (glycine, methionine, phenylalanine, etc.) will be used in the determination of the metabolism of these substances in individuals including those with cancer and alterations in metabolism. Carbon^{14} labeled uric acid and related substances will be used in the determination of body pools and turnover rates in patients with gout and related diseases.

The possession limits for Iodine^{131} is 200 millicuries, for Phosphorous^{32} 100 millicuries, Gold^{198} 600 millicuries, Carbon^{14} 10 millicuries, Cobalt^{60} 200 microcuries, Tritium (H^3) 1 microcurie. Total quantity is 10 millicuries.

I regret that the wording of our application was misleading. We do not intend to use chromic phosphate in blood dyscrasias.

With reference to paragraph 5., we do not have a separately written administrative procedure for the work of the Isotope Committee. Committee members are provided with the relevant Atomic Energy Commission publications. The function of the Committee is advisory and I am personally in direct charge of the handling of the isotopes. With regard to the specific information requested in this same paragraph I transmit the following:

1. The responsibility of the Committee as mentioned above is advisory.
2. The full Committee meets from time to time when there is sufficient business to transact. The intervals may range from a few months to nearly a year.
3. The actual handling of isotopes for human use is done entirely by qualified personnel within the Clinical Radioisotope Center or by trainees under the immediate supervision of the qualified physicians of the Clinical Radioisotope Staff. Therefore, for physicians other than trainees, our policy is to determine whether they have had a sufficient clinical experience, (i.e., the Atomic Energy Commission requirements), and if they have not, make arrangements

for them to receive it, under supervision. When a physician has a sufficient clinical experience the Committee reviews his qualifications. This is usually done by circulation although if there are any important questions they are reviewed at an actual meeting. If the Committee is satisfied that the physician is in fact qualified to recommend dosage of the designated isotope a recommendation is prepared and forwarded to the Hospital Advisory Committee, Vanderbilt University Hospital. If this recommendation meets with the Advisory Committee's approval, the physician's name is added to the list of those authorized to recommend dosage in isotope therapy. Experimental uses are dealt with as an entirely separate matter and no general authority to engage in experimental work is given. Experimental uses of isotopes are under my immediate supervision. In determining the qualifications of physicians to recommend dosage the guide lines layed down in the Atomic Energy Commission Bulletin entitled "The Medical Use of Radioisotopes" is followed. Needless to say, although we do not advertise the fact, we of the staff of the Center are in a position to exercise complete control over human dosage and if a recommended dose were out of line with acceptable practice we would deal with the situation with whatever degree of tact appropriate, but under no circumstances would we permit the actual administration of excessive dosage, nor would we permit therapeutic use of any isotope in cases where such therapy was contraindicated.

4. Isotopes are procured in prestandardized form. A running inventory is maintained by preservation of all order slips, shipping tickets and appropriate entries in the laboratory therapy log book. In addition, the log book specifically shows by signature the names of the individuals who physically participated in the administration of therapeutic isotopes in order at some future time these individuals may document their experience should they wish to obtain Atomic Energy Commission license for themselves.

5. The Committee proceedings are recorded stenographically during the meeting and these transcripts are subsequently edited to become the minutes of the Committee meeting. After correction and approval by the Committee they are filed for record and for future guidance.

VANDERBILT UNIVERSITY
SCHOOL OF MEDICINE
NASHVILLE 5, TENNESSEE
OFFICE OF THE DEAN

Mr. Cecil R. Buchanan, Assistant Chief

RE:(IRB:JRB (8456).

Our present Clinical Radioisotope Center Committee is as follows:

George R. Meneely, Chairman
John C. Burch — Robert C. Hartwann — Grant W. Liddle
Herbert C. Francis — Granville W. Hudson — M. William Scott, Jr.

With regard to your sixth paragraph it is not our policy to provide stereotyped instructions to nursing personnel. When appropriate, lectures are given to our nurses and to members of our local Nurses Association and periodically we procure from the Atomic Energy Commission appropriate literature for distribution to nurses. We do not however rely upon this for the specific patient.

1. Written orders for the care appropriate to the individual are entered in the normal place for such directions, namely, the order sheet of the individual hospital chart.

2. Directions with regard to visitors, when appropriate, are also specifically indicated in the doctor's orders.

3. We avoid collection of urine and excreta from therapy cases. There is, of course, no problem in this Department with radioactive colloidal Gold except for the bladder of prostate cases which are few in number at this hospital. In the case of large therapeutic doses of Iodine specific instructions are embodied in the doctor's orders rather than by the capricious distribution of mimeographed hand-outs. Specific activity dilution with nonradioactive potassium iodide is employed. We provide a bottle of the solution for pouring into the flushing toilet before and after each use.

I trust this will provide you with the needed information, but I will be happy to clarify any further points which remain obscure.

With best personal regards, I remain,

Sincerely yours,

George R. Meneely, M.D.
Associate Professor of Medicine
Assistant to the Dean

GRM:vh