

Minutes of the
BNL Human Studies Review Committee
11 January 1978

Upton, L. I., New York

Present: D. Borg, D. Christman, H. Connell, R. Love, C. Meinhold, N.P. Rathvon, Jr.
Also Present: Alternates - G. Price, J. Stone
Secretary - C. Kerr
Excused: P. Chandra, R. Doremus, M. Miller, I. Zanzi

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The meeting was held in the Large Conference Room of the Medical Research Center and called to order by Mr. Rathvon at 1400.

The minutes of the previous meeting held on 9 November 1977 were accepted as distributed.

CIRC 150 - "Liver Function Test Using ¹²³I-monoiodotricarbocyanine (¹²³I-MIT)" - Initial. Approved subject to the consent form being amended to state the dosage to the large intestine.

CIRC 138 - "Lead-Burdened Children: Development of New Diagnostic Techniques I: X-ray Fluorescence of Bone Lead In-Vivo" - Recertification. Approved for annual recertification but not approved for human subjects until data in phantoms containing radiation dose is obtained by the Committee.

CIRC 137 - "Lead-Burdened Children: Development of New Diagnostic Techniques II: Mass Spectrometric Analysis of Quasi-stable ²⁰⁵Pb for Tracer Studies In-Vivo" - Recertification. Approval was given for Phase I. Approval was given for Phase II with the request that the Committee be furnished with information derived from Phase I.

CIRC 96 Rev. 2 - "Long Term Study of Osteoporosis and Osteogenesis Imperfecta Tarda (OIT) in Adults" - Recertification. This CIRC was approved for annual recertification. However, HSRC is in receipt of a letter from the FDA dated 12/21/77 stating that IND 13549 for Calcimar (salmon calcitonin) is discontinued. If this drug is again subjected to clinical evaluation, it is required that the FDA be notified.

CIRC 151 - "Adrenal Imaging with ¹³¹I-19-iodocholesterol" - Initial. Dr. Atkins was called into the meeting to answer various questions. This protocol was approved but not as a study to "demonstrate the effectiveness of SC-30210 in imaging adrenal glands". However, the procedure is approved for use under the following circumstances:

1. There must be an adequate procedure to assure that the patient has taken the proper dosage of Lugols' solution.
2. The consent form should be amended to state the importance and necessity of the Lugols' solution.
3. A basis for inclusion in the program should be the determination by the physician having responsibility for the care of the patient that there is evidence the patient has an adrenal disease.
4. The consent form should be amended to delete "but definitely on days 7 and 11," and add (second sentence under hazards) "While this is in the upper range of radiation doses compared to those encountered in other diagnostic procedures it is comparable to that incurred by the thyroid when iodine-131 is used for imaging the thyroid.

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5. Page 2 of 4, E, third sentence should read: "Lugols' iodine, 20 drops the night before and 10 drops T.I.D. for six weeks after each ^{131}I -iodocholesterol administration are necessary to block thyroid uptake.

The Committee would appreciate learning from Dr. Atkins whether these conditions are acceptable to him.

The Committee also noted that the Searle protocol prohibits the inclusion of minors.

CIRC 105 - "Study of the Effects of Thiazide on Essential Hypertension" - Addendum. Dr. Iwai's request to compare the action of various clastogens on peripheral blood lymphocytes obtained from hypertensive and nonhypertensive patients was approved providing the following changes are made on the consent form:

1. Purpose: The purpose of this study is to see whether there is any difference in response in the blood cells to clastogens between hypertensives and normotensives.
2. Hazards: Whenever blood is removed or a substance is injected by venipuncture, there is minor discomfort and a slight possibility of local bleeding into the tissues, pain at site, and possibility of infection.

CIRC 144 - "Evaluation of ^{18}F FDG in the Diagnosis of Disease of the Brain and Heart" - Addendum. Dr. Atkins' request to increase the dose schedule of ^{18}F -2-deoxy-2-fluoro-D-glucose to 10 mCi instead of 5 mCi was approved with the following modifications:

Consent form should be modified to cite both the estimated radiation dose to the whole body and to the organ receiving the highest dose (bladder), then comparing each of these to permissible occupational exposures.

CIRC 130 - "Evaluation of Internally Distributed Krypton-85 as a Health Hazard" - Annual Recertification. This CIRC was not approved at the 9 November 1977 meeting. The Committee requested that the consent form be revised to state the purpose and benefit to the patient. CIRC 130 was reviewed again at today's meeting and approved.

The Chairman made the following announcements.

1. As of January 1978 new HSRC members are Marilyn Miller, M.D. and Pradeep Chandra, M.D. replacing A. Upton, M.D. and A. Ansari, M.D. respectively.
2. The appointments of R. Doremus, L. Owen, D.R. Christman, J.P. Stone, and I. Zanzi to HSRC have been extended to 12/31/80.
3. The Chairman read a letter to the Committee that was addressed to Dr. Zanzi from Jean F. Curran, Diabetes Program Director for Cellular and Molecular Studies, NIH. In Ms. Curran's letter of 11/29/77, re: 1 ROI AM 20825-01 NTN entitled "Elemental Body Composition in Diabetes Mellitus" NIH expressed the concern of their reviewers about the human subject studies. Mr. Rathvon will speak to Dr. Zanzi about this matter and report back to HSRC with the outcome.

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4. "Structure-Function Studies on Actin and Myosin" - HEW Grant. A request from Dr. M. Elzinga of the Biology Department for use of tissues from human hearts obtained from Drs. J.J. Leger and B. Swynghedauw in Paris, France was approved on 6 January 1978.
5. CIRC 119 - "Disorders of Skeletal Metabolism in Hematological Diseases" - Addendum. A special request to perform measurements of total body calcium by total body neutron activation analysis and of the bone mineral content of the radius, at baseline and serially, at a frequency not greater than twice a year on patient #8-61-6R was approved on 12/15/77.

Expenses for Volunteers - Dr. Cohn's request for travel expenses on CIRC 139 and 140 was previously reviewed on 9 November 1977 and again today. The Committee has no objection in principle to pay out of the pocket travel expenses under these two CIRC's for the patients inconvenience of having to travel to and from the Laboratory. Mr. Rathvon will send Dr. Cohn a memorandum in regard to this matter.

Dave Christman, Chairman of the RDRRC informed HSRC that the annual report will be submitted shortly and that 11 subjects were studied under CIRC 139 and no adverse effects were noted. The annual report is being processed and copies will be sent to Committee members as soon as possible.

The meeting adjourned at 1630.

Respectfully submitted,



Carole L. Kerr
Secretary

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11/11/78