

Dr. Cronkite

The Medical Research Center
 BROOKHAVEN NATIONAL LABORATORY
 Brookhaven National Laboratory
 Upton, L. I., New York

MEMORANDUM

DATE: September 26, 1978

REPOSITORY Records Holding Area Bldg. 494 TO: E. P. Cronkite
 COLLECTION Cronkite's Files FROM: N. P. Rathvon, Chairman, HSRC
 BOX No. 1 SUBJECT: AD HOC COMMITTEE - M.E. Miller, Chairperson *M.E. Miller*
 FOLDER Hospital Volunteers DAILY OPERATING PROCEDURES FOR
 OUTPATIENT RESEARCH AND NORMAL
 HUMAN VOLUNTEERS.

The committee is in full agreement that most of the problems which you have outlined in your memorandum dated September 18, 1978 are already fully covered in the Rules and Regulations of the Medical Staff of the Hospital of the Medical Research Center. We would like to specifically recommend that:

1. All investigators who are not members of the Medical Staff receive and certify that they have read and understand the Bylaws, Rules and Regulations of the Medical Staff of the Medical Research Center before proceeding with any study which involves research on human subjects.
2. All outpatient research should be handled through the Research Outpatient Receptionist (ROPR) or individuals authorized by the Hospital Administrator.
3. All payment records must be separated from the medical charts so that they are not used in lieu of a more appropriate form of documentation of visits. The Medical Department should review the proposal of Ms. Harrison concerning change over from the current mode of reimbursement to a monthly payment system.

We have specifically revised the Medical Department Guidelines for CIRC's 139 and 140 and believe that these should serve as general guidelines for all research on outpatient subjects and normal human volunteers.

Dr. Chanana informed the Ad Hoc Committee that the questions related to the use of pregnant women in clinical research and consent forms will be submitted to the Medical Staff on September 26, 1978 for further consideration.

We have also revised the Medical Department Guidelines for Voluntary Blood Withdrawals and Bone Marrow Aspirations. A revised copy of these guidelines is also enclosed.

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 Enclosures

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MEDICAL DEPARTMENT GUIDELINES FOR OUTPATIENT
RESEARCH AND NORMAL VOLUNTEERS

1. Research Outpatient Receptionist (ROPR) maintains list of applicants requesting inclusion in any CIRC.
2. Investigator in charge (if not an M.D. then after consultation with the Sponsoring Physician) selects participants and then informs ROPR, or individuals authorized by the Hospital Administrator, of desired time that the patients or normal volunteers will arrive.
3. ROPR, or individuals authorized by the Hospital Administrator, will establish appointments.
4. Physician must personally meet participant, explain procedures, and endorse properly executed consent form(s).
5. When participant is scheduled, ROPR, or individuals authorized by the Hospital Administrator, notifies the department petty cashier, who prepares Petty Cash Voucher in duplicate, holds original, sends duplicate to ROPR.
 - a. Petty Cash Voucher includes name, CIRC #, amount of payment, and note: "Documentation on file at hospital".
 - b. ROPR obtains authorized initials on duplicate and gives to participant to take to department petty cashier.
 - c. Consent form(s), physician's note, personal identification form, appropriate documentation for subsequent visits and other pertinent documents are all referred to Medical Records for filing in the patient's chart.

Revised Medical Department Guidelines for Voluntary Blood
Withdrawals and Bone Marrow Aspirations

1. Research Outpatient Receptionist (ROPR) maintains alphabetical list of persons requesting inclusion in blood/marrow list (some may offer blood only and should be so indicated).
2. The term "employee" includes all those as defined in Section III, par. A, SPI 7-02 as eligible for Industrial Medicine Services.
3. Investigator (if not an M.D. then after consultation with the Sponsoring Physician) selects participants after asking pertinent questions about present health and/or examining available medical records of employee and then informs ROPR of desired time for sample taking.
4. ROPR, or individuals authorized by the Hospital Administrator, establishes appointment and reminds participant to obtain Supervisor's approval for the specific absence from work.
5. Initially physician must personally meet participant, explain procedures, set up schedule of blood withdrawals up to maximum allowable in paragraphs 8 and 9, endorse properly executed consent form and order procedures. Blood samples may be drawn by Clinical Hematology Laboratory technician but complete instructions re collection, amount of anticoagulant, special handling, etc., are the responsibility of the physician. Bone marrow samples require a CBC prior to aspiration. Bone marrow aspirations must be done by a physician.
6. Consent forms must be complete before any procedure for blood or marrow withdrawal is begun. One consent form will suffice for allowable serial withdrawals on one individual per year.
7. When participant is scheduled, ROPR, or individuals authorized by the Hospital Administrator, notifies department petty cashier who prepares Petty Cash Voucher in duplicate, holds original, sends duplicate to ROPR.
 - a. Petty Cash Voucher includes name, life #, whether blood, marrow, or blood and marrow samples, and note "Documentation on file at Hospital".
 - b. ROPR, or individuals authorized by the Hospital Administrator, obtains Physician's initials after marrow and/or Clinical Hematology Laboratory initials after blood withdrawal and gives that copy to participant to take to department petty cashier.
 - c. Consent form, physician's note, personal identification, appropriate documentation for subsequent visits, lab slips and any other pertinent document are all referred to the Medical Record Section for filing in the patient's research chart.
8. Generally employees will not be allowed to contribute more than monthly unless there is a special research requirement for more frequent contributions.
9. No employee will be allowed to contribute more than 300 ml of blood or 6 bone marrow samples per annum.

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