gational Drug, F.D.A. Approved, Form PH–1210, obtainable in the pharmacy, have it signed by the Chief of the Division to which the investigator belongs and to forward the form to the pharmacy. The pharmacy will then acquire the drug and notify the investigator if and when it is available.

The second group of drugs consists of compounds which are either not approved by the FDA for marketing and general use, or which are approved by the FDA, but not for the purpose for which the investigator intends to use it. To obtain permission for the use of such a drug it is necessary to complete the Request and Approval for Investigational Drug, Non-F.D.A. Approved, Form PH–1228, which is also obtainable from the pharmacy. This form first has to be signed by the investigator and then by the Chief of the Division to which the investigator belongs. The properly completed and signed Form PH–1228 must be then forwarded to the Chairman of the Research Drug Subcommittee. The application should be accompanied with as much informative material, in the form of reprints or information supplied by the sponsoring drug company, as possible.

The completed applications are promptly reviewed by the Research Drug Subcommittee and if the use of the drug is approved, then the investigator is notified by the Office of the Director that he can proceed with the use of the drug. (In the past, in the vast majority of instances, applications have been approved by this committee.)

It should be emphasized that only those drugs can be employed for experimental use for which proper application has been made by the sponsoring drug company or agency with the FDA. In the case of drugs that have been synthesized in a research laboratory and not by a drug company, the individual who synthesized the compound can also be the sponsor.

(NOTE.—Additions or deletions to the Hospital Formulary will be found on the last few pages of the Bulletin. Please cut out and insert the pages in the front of your formulary.)

Under no circumstances may a drug which has not been approved by the FDA for experimental use or by the Research Drug Subcommittee be employed for investigational purposes at Montefiore Hospital & Medical Center.

FRANCIS F. FOLDES, M.D.,
Chairman, Research Drug Subcommittee.

The procedure also requires that consent be obtained from a patient or his representative. Consent forms are available from the Pharmacy. They should be made out in duplicate, the original should be placed with the patient's chart and the duplicate serving as the physician's copy for his personal records. If for some reason the physician feels that it is not feasible to obtain consent or, in his professional judgement, contrary to the best interest of these patients, a formal statement (using Form OD–1158, available in the pharmacy) must be submitted to the Chairman of the Research Drug Subcommittee stating the reason for this decision.

The procedure concerning patient consent is required by the Food and Drug Administration. This procedure should be adhered to for it protects the physician and the hospital as well as the patient if a question of liability arises.

The Pharmacy Department is responsible for packaging, labeling and distributing the drug in accordance with the requirements arranged with the investigator and only to other authorized physicians. We are happy to assist physicians with details involved in double blind studies and in many cases maintain the codes for these studies. Since the pharmacy is now open 24 hours a day, it is valuable to have this information in a central location should an emergency arise. We will, of course, maintain records of the distribution of the drug for the investigator, and provide the nurses with basic information concerning the drug since such information is not available in any of the general reference books.

The Research Drug Subcommittee will allow an investigator to maintain his own supply of a drug only in special cases provided that it has assurance that adequate controls will be maintained. We would like to discourage physicians from this practice, if for no other reason than that the pharmacy will invariably receive a call from a nursing unit requesting an additional supply of a research drug which is not available in the pharmacy and the physician cannot be located. In many instances the course of therapy is then interrupted.