STATEMENT OF PRINCIPLES INVOLVED IN
THE USE OF INVESTIGATIONAL DRUGS
IN HOSPITALS

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Hospitals are the primary centers for clinical investigations on new
drugs. By definition these are drugs which have not yet been released by
the Federal Food and Drug Administration for general use.

Since investigational drugs have not been certified as being for gen-
eral use and have not been cleared for sale in interstate commerce by
the Federal Food and Drug Administration, hospitals and their medi-
cal staffs have an obligation to their patients to see that proper pro-
cedures for their use are established.

Procedures for the control of investigational drugs should be based
upon the following principles:

1. Investigational drugs should be used only under the direct super-
vision of the principal investigator who should be a member of the
medical staff and who should assume the burden of securing the neces-
sary consent.

2. The hospital should do all in its power to foster research con-
sistent with adequate safeguard for the patient.

3. When nurses are called upon to administer investigational drugs,
they should have available to them basic information concerning such
drugs—including dosage forms, strengths available, actions and uses,
side effects, and symptoms of toxicity, etc.

4. The hospital should establish, preferably through the pharmacy
and therapeutics committee, a central unit where essential informa-
tion on investigational drugs is maintained and whence it may be
made available to authorized personnel.

5. The pharmacy department is the appropriate area for the storage
of investigational drugs, as it is for all other drugs. This will also pro-
vide for the proper labeling and dispensing in accord with the in-
vestigator's written orders.