

ARMY REGULATION

No. 40-7

HEADQUARTERS  
DEPARTMENT OF THE ARMY  
WASHINGTON, DC., 15 November 1964

## MEDICAL SERVICE

## CLINICAL USE OF INVESTIGATIONAL DRUGS

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**1. Purpose and scope.** This regulation prescribes the policies and procedures applicable to all clinical use of investigational drugs under the auspices of the Department of the Army.

**2. Definitions.** For the purpose of this regulation, the following definitions apply:

*a. Drug.* Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; and any substance (other than food) intended to affect the structure or any function of the human body.

*b. Investigational drug.* A new drug, not yet approved by the Commissioner of Food and Drugs, Department of Health, Education, and Welfare (hereinafter referred to as FDA) for general use by the public as a safe and efficacious drug, and that is proposed for clinical study under Department of

the Army auspices after adequate preclinical information has been obtained.

*c. Clinical use.* The administration of a drug to man.

**3. Procedure to be followed.** *a. Approval.* The clinical use of an investigational drug may be authorized only upon written approval of The Surgeon General (see also par. 7b). Each investigator who requests authority to conduct or is officially requested to conduct either the clinical pharmacology or clinical trials of an investigational drug will submit a signed completed application and three copies, indorsed by the hospital or other medical facility commander, to The Surgeon General, ATTN: Chairman, Army Investigational Drug Review Board (AIDRB), Department of the Army, Washington, D.C., 20315, using the following format:

*Investigator's Statement*

## I. Background data.

A. Name of investigator.

B. Date of request.

C. Name or other clear identification of drug.

D. Name of manufacturer or other source of drug.

E. Qualifications of investigator in detail or by reference to details already on file in Army records.

F. Name and address of facility or facilities where investigations will be conducted.

G. All known relevant information about past use or pertinent reference thereto available to both the investigator and the drug supplier, including all preclinical data, and all other information justifying the clinical investigation (i.e., the safety and rationale of the proposed study).

\*This regulation supersedes paragraph 795, AR 40-2, 4 November 1960.

TAGO 677A—Nov. 750-489—84

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to 7208

## II. Plan and Conduct of Proposed Clinical Investigation.

- A. Specific purpose and military need for or urgency of proposed clinical investigation.
- B. Approximate number of subjects, their age, sex, condition, and other pertinent information relevant to the conditions of the investigation.
- C. Number of subjects to be employed as controls (if any) and some information as in B above for such controls.
- D. An outline of the phases of the investigation already planned either in detail or by reference to details already on file in Army records. This outline may include reasonable alternates and variations, and will be supplemented or amended when any significant change in direction or scope of the investigation is undertaken.
- E. Description or copies of forms used to record data.

*b. Review and evaluation.* The AIDRB will review and evaluate all proposals received, enter into any indicated correspondence with the investigator, and, to the extent that the proposal is rejected in whole or in part, will transmit same to the investigator. To the extent that the AIDRB approves a proposal, it will transmit its recommendation to The Surgeon General, who will then confirm or disaffirm in whole or in part the Board's approval of the proposal in question.

*c. Bases for disapproving proposals for investigational drug—studies.* Either the AIDRB or The Surgeon General may withhold approval to study an investigational drug clinically if it is determined—

- (1) That there is substantial evidence to show the drug to be too dangerous for use for the purposes and in the manner for which it is proposed for investigational use.
- (2) That the manufacturing methods are inadequate to maintain appropriate standards of quality needed to assure safety and give significance to the clinical investigation of the drug.
- (3) That the overall plan for clinical investigation does not appear reasonable or otherwise worthy of support.

**4. Composition of Board (AIDRB).** The board will be composed of the Special Assistant to The Surgeon General for Research and Development or his personally selected designee as Chairman, and at least four other professionally qualified individuals designated by The Surgeon General, all of whom will serve at The Surgeon General's pleasure, and one of whom will be designated as the Recorder.

**5. Record-keeping requirements.** *a. By investigator.* Each investigator subject to this regulation will maintain a record of clinical investiga-

tion separate from the patient's clinical record. This record of clinical investigation will include, minimally, a list of patients receiving the investigational drug; the name, lot number, date and quantity of investigational drug prescribed; case histories; the details of clinical observations, tests, and laboratory procedures carried out on each subject before, during, and after administration of the drug in question.

*b. By custodian.* A complete record of each investigational drug will be maintained by an official designated by the commanding officer of the medical unit or installation, normally the pharmacy officer, if the investigational drug is being used in an Army facility, and by the investigator himself, or a responsible individual designated by him for the purpose, when the drug is being used under a Department of the Army contract or grant. This record will include the following information:

- (1) Name of drug.
- (2) Manufacturer, or other source of drug.
- (3) Amount and date received.
- (4) Expiration date, if any.
- (5) Lot or control number.
- (6) Date of authority to use.
- (7) Names of individuals authorized to prescribe the drug.
- (8) Name of prescribing physician or dentist.
- (9) Date on which use of the drug is terminated, if applicable.
- (10) Date on which use of the drug is approved for general use as a safe and efficacious drug, if during course of investigation.

*c. Retention period.* All records required by this paragraph will be kept 3 years after completion of the project and then retired permanently. See AR 345-210, File No. 903-38.

**6. Reporting requirements.** Progress reports will be submitted to The Surgeon General, ATTN: Chairman, AIDRB, by the responsible investigator at least once annually. A final report will also be submitted by the investigator to the Army Investigational Drug Review Board promptly on termination of the investigation. In addition, unusual or important observations will be reported promptly to such Board, particularly if they involve any adverse effect that may be regarded as caused by the new drug; if the adverse effect is alarming, it will be reported to such Board immediately.

**7. Special conditions applicable to clinical investigations of new drugs.** *a.* The investigator will make certain that the investigational drug is administered to subjects only under his personal supervision or under the supervision of other qualified personnel to whom he has delegated this authority.

*b.* The investigator will make certain that all subjects participating in the investigation or their representatives are fully informed and understand that the new drug is being used for investigational purposes. He will obtain the written consent of the subjects, or their representatives, except where this is not feasible, or, in the investigator's professional judgment, is contrary to the best interests of the subjects. When the purpose of administering an investigational drug is not to benefit the individual to whom it is administered, final approval for the use of volunteer subjects will be obtained as provided in paragraph 6, AR 70-25. Benefit to the individual is defined as the administration of a drug to an individual expected to result in the diagnosis, mitigation, treatment, cure, or prevention of disease or injury of the same individual.

**8. Information to be furnished FDA.** The Surgeon General will furnish information copies of the following to authorized representatives of FDA, provided personnel security clearances, if needed, are obtained:

*a.* Alarming and other adverse reports to The Surgeon General on the effects of an investigational drug when received.

*b.* Any existing Department of the Army report concerning an investigational drug specifically requested by an authorized representative of FDA.

*c.* In the case of unclassified clinical studies of investigational drugs, The Surgeon General will

transmit copies of the "Investigator's Statement," signed copies of the AIDRB's and The Surgeon General's evaluation and approvals to the Commissioner of Food and Drugs, Department of Health, Education, and Welfare, Washington, D.C., 20203. In the case of classified clinical investigations of new drugs, and in the case where the investigational drug to be studied is being sponsored by the pharmaceutical industry, such materials need not be transmitted to FDA, subject to the provisions of *a* and *b* above, but Form FD 1571 (see 28 Federal Register 179), FDA's usual claim for exemption, will be forwarded to The Surgeon General for transmittal to FDA after approval by The Surgeon General.

*d.* Nothing herein should be construed as precluding The Surgeon General or his delegate from transmitting any Department of the Army information pertaining to investigational drugs which, in their discretion, appears should be of interest to FDA.

**9. Medical emergencies.** In crucial situations The Surgeon General, ATTN: MEDPS-CM, may approve short term use of an investigational drug being sponsored by a pharmaceutical firm on an individual patient, without submission of the Investigator's Statement prescribed in paragraph 3, upon a hospital commander's request for same. Such request will include the following information minimally: patient's name, diagnosis, name and quantity of the drug proposed for use, medical officer responsible for the patient, and nature of the medical emergency. In cases where The Surgeon General approves emergency use of an investigational drug being sponsored by a pharmaceutical firm, the responsible investigator will furnish both a completed FD 1573 (Statement of Investigator (see 28 Federal Register 179)) to the sponsoring pharmaceutical firm and a signed copy of said Form FD 1573 to The Surgeon General as expeditiously as circumstances permit.

**10. Custody and dispensing of investigational drugs.** Investigational drugs in the custody of the Department of the Army will be stored and dispensed in accordance with the applicable provisions of AR 40-2, subject to the provisions of paragraph 5 above.

**11. Army contracts.** All contracts under which investigational drugs are to be clinically investigated will contain the following clause:

## CLINICAL STUDY OF INVESTIGATIONAL DRUGS

a. The Contractor agrees that before undertaking to conduct either the clinical pharmacology or clinical trials of an investigational drug under a Department of the Army contract, it will submit for the written approval of The Surgeon General, Department of the Army, a signed completed application and three copies to The Surgeon General, ATTN: Chairman, Army Investigational Drug Review Board, Department of the Army, Washington, D.C., 20315, using the following format:

### *Investigator's statement*

#### I. Background data.

- A. Name of investigator.
- B. Date of request.
- C. Name or other clear identification of drug.
- D. Name of manufacturer or other source of drug.
- E. Qualifications of investigator in detail or by reference to details already on file in Army records.
- F. Name and address of facility or facilities where investigations will be conducted.
- G. All known relevant information about past use or pertinent reference thereto available to both the investigator and the drug supplier, including all preclinical data, and all other information justifying the clinical investigation (i.e., the safety and rationale of the proposed study).

#### II. Plan and Conduct of Proposed Clinical Investigation.

- A. Specific purpose and military need for or urgency of proposed clinical investigation.
- B. Approximate number of subjects, their age, sex, condition and other pertinent information relevant to the conditions of the investigation.
- C. Number of subjects to be employed as controls (if any) and same information as in B above for such controls.
- D. An outline of the phases of the investigation already planned either in detail or by reference to details already on file in Army records. This outline may include reasonable alternates and variations, and will be supplemented or amended when any significant change in direction or scope of the investigation is undertaken.

#### E. Description or copies of forms used to record data.

b. The Contractor agrees that each of its investigators who conduct either the clinical pharmacology or clinical trials of an investigational drug will maintain a record of clinical investigation separate from the patient's clinical record. This record of clinical investigation will include, minimally, a list of patients receiving the investigational drug; the name, lot number, date, and quantity of investigational drug prescribed; case histories; the details of clinical observations, tests, and laboratory procedures carried out on each subject before, during, and after administration of the drug in question.

c. The Contractor agrees also that either its responsible investigator or a responsible individual designated by him for the purpose will maintain a complete record of each investigational drug used under a DA contract for at least 3 years after completion of the investigational drug study. This record will include the following information:

1. Name of drug.
2. Manufacturer, or other source of drug.
3. Amount and date received.
4. Expiration date, if any.
5. Lot or control number.
6. Date of authority to use.
7. Names of individuals authorized to prescribe the drug.
8. Names of prescribing physician or dentist.
9. Date on which use of the drug is terminated, if applicable.
10. Date on which use of the drug was approved for general use as a safe and efficacious drug, if during course of investigation.

d. The Contractor agrees to submit progress reports to The Surgeon General, ATTN: Chairman, AIDRB, at least one annually, and to submit a final report on termination of the investigation. In addition Contractor agrees to promptly report to the AIDRB any unusual or important observations occurring during the course of the investigational drug study.

particularly if they involve any adverse effect that may be regarded as caused by the new drug; if the adverse effect is alarming, it will be reported to the AIDRB immediately.

e. **Special Conditions Applicable to Clinical Investigation of New Drugs:** The Contractor agrees to make certain that the investigational drug is administered to subjects only under the personal supervision of the responsible investigator or a qualified person to whom the responsible investigator has delegated this authority. The Contractor also agrees to make certain that all subjects participating in the investigation or their representatives are fully informed and understand that the new drug is being used for investigational purposes. The written consent of the subjects, or their representatives will be obtained except where this is not feasible or, in the responsible investigator's professional judgment, is contrary to the best interests of the subject. When the purpose of administering an investigational drug is not to benefit the individual to whom it is administered, final approval for the use of volunteer subjects will be obtained as provided in paragraph 6, AR 70-25. Benefit to the individual is defined as the administration of a drug to an individual expected to result in the diagnosis, mitigation, treatment, cure, or prevention of disease or injury of the same individual.

12. **Army grants.** All Department of the Army grants under which investigational drugs are to be clinically investigated will contain clauses requiring the grantee to comply with the requirements of paragraphs 3, 5, 6, and 7.

[MEDJA]

By Order of the Secretary of the Army:

HAROLD K. JOHNSON,  
*General, United States Army,*  
*Chief of Staff.*

Official:

J. C. LAMBERT,  
*Major General, United States Army,*  
*The Adjutant General.*

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*USAR:* None.