DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY HEALTH SCIENCES COMMAND
Fort Sam Houston, Texas 78234-6000

HSC Supplement 1
to AR 40-38

12 December 1991

Medical Services
CLINICAL INVESTIGATION PROGRAM

Issue of supplements to this regulation by subordinate commanders is prohibited, unless specifically approved by HQ HSC, ATTN: HSHN-I.

AR 40-38, 1 September 1989, is supplemented as follows:

Page 3, Paragraph 2-7b, Commander, U.S. Army Health Services Command. Add subparagraphs (1) and (2).

(1) The Clinical Investigation Program Division (CIPD) performs quality assurance review on all protocols and "loan agreements" generated by HSC Clinical Investigation Departments. Local Judge Advocate approval of "loan agreements" is required.

(2) The CIPD review may question, or suspend any protocol, to include locally approved protocols, request additional information, delay, or disapprove any protocol which does not meet regulatory guidelines. Any request for additional information, suspension, or termination will be made within 30 days of receipt at the CIPD.

Page 3, Paragraph 2-7c, Commander, U.S. Army Health Services Command. Add subparagraphs (4) and (5) after subparagraph (3).

(4) Execute local approval authority for Group C Cancer Chemotherapy Investigational Drug Protocols (excluding tetrahydrocannabinol (Marijuana/THC)), provided the following conditions are satisfied:

(a) The investigator(s) has been accepted by National Cancer Institute.

(b) The local Human Use Committee (HUC) has recommended approval of the study.

(c) The local commander has approved the HUC minutes.

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* This Supplement supersedes HSC Regulation 40-23, all changes, and all previous policy letters pertaining to the Clinical Investigation Programs and their funding.

(5) Forward all protocols (irrespective of their classification, (e.g.) expedited and exempt) within 30 days of local approval to Commander, HCSCIA, ATTN: HSHN-I, Fort Sam Houston, TX 78234-6060. Each submission of protocols to the CIP will include:

(a) Two copies of each protocol.

(b) A summary of committee actions.

(c) A listing by classification.

(d) Identification of protocols requiring approval by HSC, or other organizations.

Page 4, Paragraph 2-10c, HSRRB, HURRAO, and Investigations. Add subparagraphs (14) and (15) after subparagraph (13).

(14) Apprise the HUC within 30 days of study completion, discontinuance or when a change of principal investigator is anticipated.

(15) Upon completion/termination of study, provide the following documents to the department/service providing clinical investigation support.

(a) Original signed DA Form 5303-R (Volunteer Agreement Affidavits).

(b) Case report forms for all Drug/Device studies.

(c) A summary of results, including all Adverse Reaction Reports.

Page 5, Paragraph 3-5d, Conducting CIPs involving humans. Add subparagraph (7) after subparagraph(6).

(7) The chairman of the HUC will ensure that all "exempt" and "expedited" protocols fulfill the requirements for those categories as prescribed in appendices B and H.

Page 5, Paragraph 3-5e, (8) Conducting CIPs involving humans. Change the second sentence to read as follows:

CIs requiring TSG or higher level approval will be forwarded through: Commander, HCSCIA, ATTN: HSHN-I, Fort Sam Houston, TX 78234-6060; to the Assistant Surgeon General for Research and Development, c/o Commander, U.S. Army Medical Research and Development Command, ATTN: SGRD-HR, Fort Detrick, Frederick, MD 217010-5012.

Page 15, Appendix D, Add subparagraphs D-7 through D-9 after subparagraph D-6. Reporting Format for the Annual Progress Report (Clinical Investigation Program, RCS MED-300 LRI).

D-7. **Due Date.** Annual reports will be distributed as described in subparagraph D-8, and within 120 days of the beginning of each fiscal year.

D-8. **Distribution***

No. copies	Agencies
1	Commander US Army Medical Research and Development Command ATTN: SGRD-HR Fort Detrick Frederick, MD 21702-5012
2	Defense Technical Information Center ATTN: DTIC-FDAB Cameron Station Alexandria, VA 22304-6145
2	Commander Health Care Studies and Clinical Investigation Activity ATTN: HSHN-I Fort Sam Houston, TX 78234-6000
1	Each U.S. Army Medical Center Department of Clinical Investigation

*This list represents a minimum distribution list.

D-9. **Report Guidelines.**

I. FRONT COVER

II. TITLE PAGE

III. FORWARD

IV. UNIT SUMMARY:

a. Objectives.

b. Technical Approach.

c. Staffing (name if filled, rank, title, authorized Military Occupational Specialty).

d. Funding Report:

Civilian Personnel	$000,000	Grants USAMRDC	$000,000
Operations	$	" Federal	$
CEEP	$	" Non-federal	$
Other OMA	$	Medcase	$
		Mil Personnel	$
		Other Non-OMA	$
OMA Total	$000,000	Non-OMA Total	$000,000

e. Progress.

f. Problems.

V. Table of Contents (list by department, indicate year initiated, current disposition; ongoing (O), terminated (T), completed (C), submitted for publication (SP), or published (P)).

VI. Publications for the report year (listed by department or service). Publications resulting from clinical investigation projects are coded (C).

VII. Presentations (listed separately using the same convention as in VI. above).

VIII. Detail sheets (for MEDCEN protocols).

Detail Summary Sheet

Date: Prot No: Status:
Title:

Start Date: Est Comp Date:
Principal Investigator: Facility:

Dept/Sec Assoc Investigators:

Key words
Accumulative MEDCASE Cost: Est Accumulative OMA cost: Periodic Review Results
*Study Objective:

*Technical Approach:

Progress:

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*Complete or abstract report. Continuation sheets may be used.

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IX. Detail sheets (for Medical Activity protocols using the Medical Center format).

X. Index:

a. Subject.

b. Author.

XI. Back Cover.

Page 17, Appendix F, Paragraph F-5, Human Use Committee. Add paragraph d after paragraph c.

d. Ensure that pregnancy testing is performed on all female subjects when pregnancy is an exclusion criteria, or when contraindicated during treatment with the drug or device being tested or evaluated. Ensure that a negative pregnancy test is obtained no more than 48 hours prior to the administration of an investigational drug or vaccine. Further, whenever possible, administration of investigational drugs and vaccines should occur during menses.

Page 22, Glossary, Section II Terms. Add the following:

CHILD Any person, other than an active duty military member, who has not attained the legal age of consent to general medical care as determined under the applicable law of the jurisdiction in which such study is to be conducted.

GROUP C CANCER CHEMOTHERAPY INVESTIGATIONAL AGENTS Drugs that demonstrate efficacy within a tumor type in more than one study, which alter the pattern of care or the disease in question, and are safely administered by properly trained physicians without requiring specialized supportive care facilities. The classification of an investigational drug into Group C and its distribution is administered by the NCI.

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Proponent Block

The proponent agency of this supplement is the Health Care Studies and Clinical Investigation Activity. Send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, U.S. Army Health Care Studies and Clinical Investigation Activity, ATTN: HSHN-I, Fort Sam Houston, Texas 78234-6060.

FOR THE COMMANDER

OFFICIAL:

PHILIP L. DORSEY
Colonel, MS
Chief of Staff

MARY KAY JONES
CPT, AG
Chief, Administrative Services Division

DISTRIBUTION:
HSC Form 17 Distribution (attached)

SPECIAL DISTRIBUTION:
HSIM-SO (50 cy)
HSIM-SO (Library 1 cy)