



DEPARTMENT OF THE ARMY
U.S. ARMY HEALTH CARE STUDIES AND CLINICAL INVESTIGATION ACTIVITY
FORT SAM HOUSTON, TEXAS 78234-6060

ARM1.950119.012a

HSHN-I (40-38a)

12 February 1993

MEMORANDUM THRU Commander, William Beaumont Army Medical Center, ATTN: DCCS,
El Paso, TX 79920-5001

FOR Commander, William Beaumont Army Medical Center, ATTN: Chief, Clinical
Investigation, El Paso, TX 79920-5001

SUBJECT: Request for Permission For One-Time Use of An Investigational Drug

1. Reference AR 40-7, 4 Jan 91, Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances, paragraphs 4-9 through 4-11.

2. On 12 February 1993, I was contacted by COL Manuel Schydlower, MC, William Beaumont Army Medical Center (WBAMC), 915-569-2233, requesting permission for the one-time use of an investigational drug.

3. As prescribed in AR 40-7, I considered the information in paragraph 4 and the request for approval of the use of the named investigational drug.

4. Specific information regarding this case:

- a. Patient's Name: , 34 months old
- b. Diagnosis: Acute lymphocytic leukemia (ALL)
- c. Drug: Erwinia asparaginase, under IND I91-7- 646
- d. Source: National Cancer Institute
- e. Dose: 25,000 IU/M² IM weekly for 20 weeks
- f. Investigator/Attending Physician: Jerry J. Swaney, MD, Department of Pediatrics (979-2283)
- g. Nature of Use: Patient developed an allergic rash to asparaginase produced by *Escherichia coli*. Erwinia asparaginase is to be substituted for the *E. coli*-based product for the remainder of the protocol.

privileged information
IPAW
Privacy Act of 1976

5. In considering this request, I also note that two previous requests for one-time use of this drug from WBAMC were approved on 21 August 1992. After due consideration of the above information, I approve this one-time use of the named investigational drug for the named patient. This approval is contingent on Dr. Swaney filing a protocol with WBAMC's institutional review board and, if appropriate, joining in the research protocol of the sponsor, the National Cancer Institute.

6. The investigator/attending physician cited above must abide by requirements of paragraphs 4-9 through 4-11 of AR 40-7. The officer must describe to the Clinical Investigation Program Division the circumstances and outcome of the use of this investigational drug, as well as provide copies to CIPD of any related forms or reports furnished to any commercial manufacturer or sponsor, other agencies, or individuals.

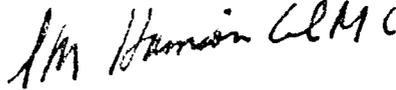
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HSHN-I

SUBJECT: Request for Permission For One-Time Use of An Investigational Drug

7. My point of contact is MAJ John D. Grabenstein, DSN 471-2511 or commercial (210) 221-2511 or -0628, Clinical Investigation Program Division.



SHANNON M. HARRISON

COL, MC

Chief, Clinical Investigation
Program Division

CF:

HQDA, ATTN: SGPS-CP-M, 5109 Leesburg Pike, Falls Church, VA 22041-3258

HQDA, ATTN: SGRD-HR, Fort Detrick, Frederick, Maryland 21702-5001

CDR, WBAMC, ATTN: HSHM-DCI, El Paso, TX 79920-5001



DEPARTMENT OF THE ARMY
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920-5001

REPLY TO
ATTENTION OF:
(40-38)

HSHM-DCI

12 February 1993 (date)

MEMORANDUM THRU Commander, William Beaumont Army Medical Center,
El Paso, TX 79920-5001

FOR Cdr, USA Health Care Studies, Clinical Investigation Activity,
Ft. Sam Houston, TX 78234-6060

SUBJECT: REQUEST FOR EMERGENCY USE OF IND

IAW provision of AR 40-7, request approval for emergency IND use as follows:

a. Patient Name: SSN:
Age: 34 months Sex: F

b. Diagnosis: Acute Lymphoblastic Leukemia

c. IND Name: Erwina Asparaginase IND #: I 91-7-~~446~~

Quantity: 9 10000 unit vials

Source: NCI

Medical Officer Responsible for Patient: Dr. Swaney

Nature of Emergency: Patient is allergic to E. Coli L. Asparaginase



JERRY SWANEY, MD (Med Officer Signature)

Staff Physician (Typed Name)

Pediatrics (Rank, Corps)

Pediatrics (Department)

**National Cancer Institute
Division of Cancer Treatment, CTEP
Investigational Drug Branch
Drug Management and Authorization Section
(301) 496-5725**

Policy For Group C Drug Distribution

Group C agents are investigational drugs provided by the National Cancer Institute to properly trained physicians for the treatment of individual patients who meet the eligibility criteria. Agents within this category have been approved by the Food and Drug Administration for the treatment of the specific cancer identified in the guideline protocol.

Group C drugs are provided for the treatment of patients as indicated below:

<u>Drug</u>	<u>Approved Group C Use</u>
a) Amsacrine*	Refractory Adult Acute Myelogenous Leukemia (AML) Single agent use only
b) Azacytidine*	Refractory Acute Myelogenous Leukemia (AML) Single agent use only
c) 2-Chlorodeoxyadenosine* (2-CDA)	Active Hairy Cell Leukemia Single agent use only
d) Erwinia Asparaginase*	Acute Lymphoblastic Leukemia (ALL), for patients allergic to E. Coli L- Asparaginase
e) Teniposide*	First Relapse or Refractory Acute Lymphocytic Leukemia (ALL) Combination therapy with cytarabine

* The FDA has granted a waiver from local IRB Approval. See paragraph 5 on the next page.

Revised 5/07/92

Group C drugs will be provided to investigators in accordance with the following policy guideline:

1. A physician must be registered with the National Cancer Institute as an investigator by having completed a Statement of Investigator, Form FDA 1572. Physicians not currently registered will be sent a Group C drug with the understanding that they will complete and return their registration within 10 working days of its receipt.
2. Physicians may obtain any drug listed by telephoning the Drug Management and Authorization Section of the Investigational Drug Branch. The telephone number is (301) 496-5725. (M-F 9-4pm EST)
3. Written informed consent must be obtained from all patients treated with Group C drugs and kept on file by the physician.
4. Institutional Review Board (IRB) approval must be obtained when applicable. The Food and Drug Administration (FDA) has granted the NCI a waiver from the requirement for local IRB approval for those agents marked with an asterisk(*). FDA's granting of the waiver does not preclude a local IRB from exercising its prerogative to initiate its review at any time.
5. Adverse Drug Reactions: All life-threatening and lethal (grade 4 and 5) unknown (not listed in the protocol as known toxicities) adverse drug reactions must be reported by phone 301-496-7957 to the Investigational Drug Branch within 24 hours. A written report must follow within 10 working days. All grade 4 and 5 known reactions (except grade 4 myelosuppression) and grade 2 and 3 unknown reactions should be reported by mail within 10 days. An adverse drug reaction form for investigational drugs and the chart for common toxicity criteria are in the protocol appendices. All reports should be mailed to: Investigational Drug Branch; P.O. Box 30012; Bethesda, Maryland 20824.
6. NCI Investigational Drug Accountability Records must be maintained for Group C drugs and kept on file by the physician.
7. Records to confirm that the patient has been treated according to the Group C protocol must be maintained by the physician. NCI or the FDA may have access to these records upon request.