MCHL-CI (40-38a) 18 March 1997
(Revised 26 October 2007)

MEMORANDUM FOR STAFF PHYSICIANS, WRAMC

SUBJECT: Emergency One Time Use of an Investigational New Drug (IND) or Device (IDE)

1. References:

a. AR 40-7, "Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances," (revised 4 January 1991).

b. FDA Information Sheet, "Emergency Use of an Investigational Drug," October 1995, Updated 1998.

2. The following guidance is provided to clarify physician responsibilities for the one time use of an investigational new drug (IND) or an investigational device (IDE) as set forth by the Department of the Army and the Food and Drug Administration (FDA). If you are requesting approval of an investigational device, substitute IDE for IND and device for drug.

a. An "emergency medical situation" is defined as one in which (1) a single patient has a life-threatening condition, (2) a physician wants to use a drug not approved for general use by the Food and Drug Administration, and (3) there is insufficient time to submit a protocol to the Human Use Committee (HUC).

b. An "IND" is a drug that is available for use only under a "Notice of Claimed Investigational Exemption for a New Drug" approved by the FDA.

c. If an investigational new drug is being considered for use in a single patient, the attending staff physician responsible for the patient must determine that the drug offers an opportunity for patient benefit beyond that of a marketed alternative.

d. An IND number must be obtained. Whenever possible, this should be accomplished by using the drug under a third party IND (usually a manufacturer's IND) with their approval. Contact the manufacturer and ask for approval to use their IND on a one-time emergency use basis. If they cannot provide you with the IND number because an application is pending approval, you should ask for the name and phone number of the medical officer at the FDA who is processing the application and contact that person for the IND number. If an IND application has not been submitted by the manufacturer, you should contact the FDA, Division of Emergency and Epidemiological Operations, at (301) 443-1240.

e. The investigational new drug must be shipped to and dispensed by the WRAMC Pharmacy, and devices should be shipped to DCI.

f. The Chief, Clinical Investigation Regulatory Office (CIRO), is the final approval authority for the use of an investigational new drug in a single individual patient upon request from an Army medical facility commander. At WRAMC, the Department of Clinical Investigation (DCI) acts on behalf of the Commander, WRAMC, and the HUC to provide local clearance.

g. Approval of an IND in an emergency situation is granted only for one time use. If patient care needs dictate use of the IND at a later time or in another patient, the FDA requires approval of a clinical investigation protocol application by the WRAMC HUC.

3. The following steps must be followed and information obtained by a physician who wants to use an IND in an emergency medical situation.

a. Obtain the patient's voluntary and informed consent to use of the investigational new drug, documented in the patient's chart. The standard DA Form 522, "Request for Administration of Anesthesia and for Performance of Operations and Other Procedures," should be used (see example at Encl 1). **Do not use the sponsoring company's consent form.**

b. Contact the Chief or Asst. Chief of DCI for local clearance and authorization to contact CIRO. Provide both sources with the following information:

[**NOTE:** POC is MAJ, MC, Assistant Chief, DCI, on 782-7858 or COL, MC, Chief, DCI, on 782-6389 during duty hours; Alternate POCs are COL, MC at 782-5603 or COL, MC at 782-6369/2739; after duty hours contact the AOD on 782-7309 who will provide on-call telephone numbers for the above.]

(1) Name, diagnosis, and SSN of patient.

(2) Name, dosage, length of use, and source of the drug.

(3) IND number for the use of the investigational new drug (obtained per instructions in para 2.d. above).

(4) Name of the responsible staff physician.

c. Document the date and time of local clearance from DCI.

d. Notify the Pharmacy Service of incoming investigational drugs (782-7400/3835, 0800-1700) and (782-6421 after 1700) or DCI (Chief, Research Review Service, 782-7858) for incoming devices.

e. **Contact CIRO for final approval.**

[**NOTE:** POC is COL or COL; autovon 471-2511/9302 or commercial (210) 221-2511/9302. The CIRO fax is (210) 295-0244. After duty hours, the CIRO Regulatory Staff Office is on call

24 hours a day via pager (210)-613-1442 (Digital) or cell phone (210)-380-8206.

f. Submit a memorandum to CIRO through DCI within one working day (Use provided initial request memorandum template in the Emergency.doc file).

g. A follow-up written report that includes the outcome of the use of the IND must be submitted to DCI within 10 days of the end of IND treatment or after 6 weeks of initiating the drug (Use provided follow-up report memorandum template also in the Emergency.doc file). Include copies of any forms or reports furnished to a drug company or other non-DA agency in connection with this drug use.

4. If you have questions, please contact the undersigned (782-6389) or R.N., Department of Clinical Investigation, at 782-7830.

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COL, MC
Chief, DCI