

UWO - HSREB	GUIDELINE	2-G-010	Page 1 of 2
Effective date: January 1, 2000 Revised for clarity: September 7, 2006	REQUESTS FOR REB APPROVAL OF COMPASSIONATE OR EMERGENCY RELEASE OF STUDY DRUGS OR TREATMENT		

*Please note that only the Director of the Office of Research Ethics or the Chair of the HSREB may give this approval on behalf of the HSREB.*

*The approval issued by the HSREB refers only to the collection, use and disclosure of confidential personal health information associated with the use of the drug or treatment on the patient under consideration.* Approvals related to the clinical appropriateness of the intervention or the approval of investigational drugs/devices must be sought from other bodies (e.g. Hospital or Health Canada), preferably prior to seeking HSREB approval.

The administration of an experimental drug or treatment outside of an approved clinical trial is a medical decision determined as the best course of action by the patient's treatment team. This is not research and therefore does not fall under the purview of the HSREB. In some cases hospitals will require that such actions be approved by the institution's medical advisory committee or a senior physician responsible for medical affairs.

The research component relevant to the mandate of the HSREB relates to the collection of data for research purposes. I.e. the sponsor requests access to the patient's personal health information to add to the pool of information on the drug or treatment. The patient or his/her legally authorized representative must consent to this collection, use and disclosure.

In order to issue a letter giving approval on behalf of the UWO Health Sciences Research Ethics Board, the Office of Research Ethics will require a request in the form of a fax, letter or email from the attending physician covering the following issues. If there is not sufficient time for written correspondence then the Chair of the HSREB or the Director of the Office of Research Ethics may alternatively get the information verbally from the physician.

- Patient's age, sex, initials
- brief description of the case (e.g. 10 year old female with massive sepsis that is non-responsive to established treatment)
- why this intervention may be helpful (e.g. previous success in older population)
- name of drug and pharmaceutical company
- name of study
- how this patient differs from population under study (and any concerns this raises)
- discuss consent issues
  - is this a vulnerable subject? E.g. child, comatose, incompetent patient?
  - who will be providing consent? Parent(s), guardian, public trustee?
  - Is there a Letter of Information available to be given to the person providing consent,
    - If yes, provide copy
    - if no, what will be done instead to provide information for consent purposes

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### **Post Crisis Report**

The physician is expected to submit a written report to the Office of Research Ethics within 7 days after the crisis has passed. This report should include:

- a description of the outcome of treatment and any adverse events related to the treatment
- and information in the request section if original request was not made in writing

All requests and correspondence should be sent to the attention of:

Director

The Office of Research Ethics

Room 00045 Dental Sciences Building

The University of Western Ontario

London, Ontario N6A 5C1

Telephone 519-661-3036

Fax 519-850-2466

Email: [ethics@uwo.ca](mailto:ethics@uwo.ca)