ADIRONDACK HEALTH

TITLE:	Emergency or Compassionate Use of an Investigational Product	POLICY #: SOP-10
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 2
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1. The **FDA** allows the use of investigational drugs outside the standard research setting in three circumstances (the Department of Health and Human Services-**DHHS**, does not allow Emergency Use but does allow physicians to treat patients with a compassionate use protocol; the same rules apply):
    1. Emergency Use (EU) exemption from IRB approval,
    2. Treatment investigational new drug application, or
    3. A parallel track mechanism (we will probably never encounter this).

2. The rules for emergency use require two elements to be present first:
    1. a life-threatening situation in which no acceptable (FDA-approved) treatment is available **and**
    2. there is insufficient time to convene a quorum for full IRB approval, therefore the test article must be used expeditiously.

If those two elements are not present, then full-board approval of the protocol and consent must be obtained before the test article can be released to the investigator. The Emergency Use provision is not a way to circumvent the IRB process.

If those two elements are present, the following procedures are required:

1. Determine whether the sponsor requires an IRB acknowledgement letter **or** an IRB approval letter. Generally, the sponsor only requires IRB acknowledgement of the use before or within 5 days after the emergency use. If they require an IRB approval letter then the full board (minimum quorum is acceptable and the scientific member must be an MD) must meet and act on the EU.

2. The Principal Investigator will generate a letter (electronic e-mail is sufficient) to the IRB Chair describing the Emergency Use situation. IRB members can see the Sample Letter to the IRB Chair for Emergency Use in their handbook.

3. The IRB Chair, after review of the letter with an IRB member with medical knowledge, will generate a letter which gives knowledge of, acknowledgement of or appropriate notification of the EU of the test article. It must also say that any subsequent use of the test article must require full IRB review and approval unless the two EU elements are present. The letter must **not** note IRB review or approval.

Acting Chair or Vice Chair can review the Sample Letter of Acknowledgement in their Handbook.

4. An informed consent is required although it may be supplied by the sponsor and may not necessarily be in the standard format for informed consents in clinical research. It is also not subject to IRB review or approval as long as the two EU elements are present. It will not be stamped with IRB approval, but will be filed.

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 56.103-105
NYCRR: N/A
HFAP: N/A