1 PURPOSE
1.1 The purpose of this policy is to distinguish “planned emergency research” and “emergency use of test articles” and to state the requirements and procedures for emergency use of test articles within AMITA Health

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 Emergency situations may arise in which there will be a need to use a test article in a manner inconsistent with the approved investigational plan or by a physician who is not part of a clinical study. FDA exempts from prospective IRB review the emergency use of a test article so long as the emergency use is reported to the IRB within five (5) working days of its occurrence. (21 CFR 56.104(c)) Provided, however, the treating physician:

3.1.1 First attempts to contact the IRB Chairperson or IRB Coordinator, if within normal business hours, to request approval to proceed with administration of the test article;

3.1.2 Evaluates the likelihood of a similar need for the emergency use occurring again, and if future use is likely, immediately initiates efforts to obtain prospective IRB approval.

3.2 If it is feasible to request prior approval to proceed with administration of the test article (i.e. within normal business hours), the attending/consulting physician must provide the following information in writing to the IRB Chairperson or IRB Coordinator, along with the drug or device protocol:

3.2.1 A certification of why the case is an emergency describing the life threatening or severely debilitating condition

3.3 Upon receipt of the request, the Chairperson or Designee of the IRB will review the protocol to ensure the request is consistent with IRB guidelines. If the guidelines are met, the IRB Chairperson or designee will approve the use of the drug or device without prospective IRB review.

3.4 In addition to obtaining the prior approval of the IRB Chairperson or his/her designee, informed consent is required to be signed by the patient or the patient’s legal representative unless the following requirements are met and documented:

3.4.1 The patient is confronted by a life-threatening situation (as defined above) necessitating the use of the test article;

3.4.2 Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent, from the subject;

3.4.3 Time is not sufficient to obtain consent from the subject’s legally authorized representative; and,

3.4.4 No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject’s life. (21 CFR 50.23(a)).

3.5 If obtaining informed consent is not possible from the patient or the patient’s legal representative, the treating physician and a physician not otherwise involved in the study of the test article must certify in writing to the IRB that the above four conditions were met:

3.5.1 If, in the treating physician’s opinion, immediate use is required to preserve the patient’s life and if time is insufficient to obtain an independent physician’s determination that the
above four conditions are satisfied, the treating physician must, within five (5) working
days, have the use reviewed and evaluated in writing by an independent physician as to
whether the above four conditions were met at the time of the emergency use.

3.6 Test articles shall only be administered by a licensed physician to a single subject as a single
course, but may involve multiple dosing to achieve maximal efficacy. Any subsequent use of the
test article is prohibited until the study is reviewed and approved by the fully-convened IRB at
AMITA Health. (21 CFR 50.23; 21 CFR 56.104(c)) Should a situation arise which would require
the emergency use of the test article for a second patient, either by the same or a second
physician, for the same test article, subsequent emergency use should not be withheld for the
purpose of gaining IRB approval. However, any use of the data obtained from the second
emergency use as part of the study results is not allowed. If it appears probable that similar
emergencies will require subsequent use of the test article at AMITA Health, every effort should
be made either to sign on to the sponsor’s protocol or to develop a protocol for future emergency
use at AMITA Health. Either of these protocols requires prospective IRB review and approval.

3.7 Within five (5) working days following the emergency use of the test article, the treating physician
shall provide the FDA or the sponsor, whichever is applicable, and the AMITA Health IRB with a
written summary of the conditions constituting the emergency, subject protection measures
implemented, and the results.

3.7.1 When the IRB receives a report of an emergency use, the IRB must examine each case
via a full panel process to assure itself and AMITA Health that the emergency use was
justified and document its findings. Emergency use reports will be reviewed at the next
scheduled meeting, unless the IRB Chairperson calls a special meeting to review the
report.

3.7.2 The IRB will forward acknowledgement of the use to the treating physician following its
review of the emergency use report.

4 RESPONSIBILITIES

4.1 Principal Investigator / Treating Physician & IRB

5 PROCEDURE

5.1 Prior approval / Notification

5.1.1 If the emergency use will occur within normal business hours, the treating physician
must make every attempt to contact the IRB Chairperson or IRB Coordinator to request
approval from the Chairperson or Co-Chairperson of the IRB to proceed with
administration of the test article.

5.1.2 The information outlined in section 3 above, must be provided at that time.

5.2 Exemption from Informed Consent Requirement

5.2.1 If obtaining informed consent from the patient or patient’s legally authorized
representative is not feasible, the treating physician and an independent physician must
certify in writing to the IRB that the four conditions listed in section 3.4 above, were met
at the time of administration of the test article.

5.2.2 If there is insufficient time to obtain the independent determination, the treating physician
shall make his or her own written determinations, and then obtain the written review and
independent evaluation within five (5) working days.
5.3 Emergency Use Report

5.3.1 Within five (5) business days following administration of the test article, an IRB “Emergency Use Report” (HRPP-217) must be completed and filed with the IRB office.

5.3.2 All emergency use reports will be reviewed by a full panel at the next scheduled meeting or at a specially convened meeting if called by the IRB Chairperson.

5.3.3 IRB acknowledgement of the use will be sent to the treating physician following its review of the emergency use report.

5.4 Subsequent use: The treating physician will evaluate the likelihood of a similar need for the emergency use occurring again, and if future use is likely, immediately initiate and submit the applicable AMITA Health IRB application for prospective review and approval to the IRB.

6 MATERIALS

6.1 Emergency Use Report (HRPP-217)

7 OTHER RELATED POLICY/PROCEDURES

7.1 Planned Emergency Use (PP-209)

8 REFERENCES

8.1 21 CFR 50.102(c) and (d)
8.2 21 CFR 50.23
8.3 21 CFR 50.24
8.4 21 CFR 59.104(c)