“Test Article” means any drug, biological product, or medical device for human use [21 CFR 56.102(1)].

“Emergency Use” means the use of a test article on a human subject in a life-threatening situation for which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102 (d)].

The Principal Investigator must submit the following materials to the IRB within five (5) working days following the emergency use of the test article:

1. Sections A--C in all cases;

2. IF informed consent was NOT obtained from participant or the legally authorized representative, arrange for an independent physician (one not participating in this trial) to complete Section D: Independent Physician Certification of Emergency Use of a Test Article Without Informed Consent. Ideally this certification is obtained before use of the test article. If time does not allow this, an independent physician should review and evaluate the decision as soon as possible but in time to allow notification of the IRB within five working days after the use of the article [21 CFR 50.23 (c)].

3. Signed Consent Form with HIPAA authorization, if obtained. (Needed because FDA may require data from an emergency of a test article in a life-threatening situation to be reported in a marketing application).

SECTION A

Principal Investigator _______________________________________________________

Title:_____________________________________________________________________

Department/School/College:___________________________________________________

Phone__________ FAX__________ Mailbox__________________________
E-mail__________________________________________________________

Alternate (Administrative) Contact: ________________________________

Phone:__________     FAX_________ E-mail______________________

PROTOCOL TITLE:__________________________________________________

__________________________________________________________________

Name of Test Article: ________________________________________________

Initials of Patient__________________________________

Subject Population:

_____ Child (under 18)        _____Mentally disabled

_____ Pregnant woman/fetus       _____Cognitively (decisionally) impaired

_____ Neonate             _____ Prisoner

_____ Other__________________________________________________

Location of Population: ___________________________________________

Was test article provided:   _____At cost?  _____Free of charge?

Section B

Radioisotopes/radiation-producing machines?      YES              NO
Human blood or body fluids?                      YES              NO
Investigational Drug or Biologic?                YES              NO

Name: _________________________________________________________

IND held by _____Sponsor    _____Investigator    IND #__________

Manufacturer_____________________________________________________

1.  Has sponsor agreed to use of this drug or biologic for this subject? YES   NO
2. Has FDA given permission for this use and this subject?    YES   NO

Investigational Device?                          YES              NO

IDE #:___________    Non-Significant Risk?    YES              NO
                                  Significant Risk?    YES              NO
1. Has sponsor agreed to use of this device for this subject?  YES  NO
2. Has FDA given permission for this use and this subject?  YES  NO
   If YES, attach FDA IDE letter.

SECTION C
Principal Investigator Certification: Emergency Use of Test Article with Informed Consent

Date of use of test article:_________________________________________

1. I certify that all of these statements are true:

   _____ The participant was confronted by a life-threatening or severely debilitating situation and necessitating the use of the test article.

   Explain:

   _____ No alternative method of approved or generally recognized therapy was available that provides an equal or greater likelihood of saving the participant’s life.

   Explain:

   _____ There was not sufficient time to obtain IRB approval in advance for use of the test article.

   Explain:
Any subsequent use of the test article is subject to full prospective IRB review.
If you intend to use the test article in the future, you must submit an application to the IRB for full board review.

Informed Consent

1. Was informed consent obtained from the participant or the legally authorized representative?
   - YES  Date consent obtained: __________________________
   - OR
   - Documentation of Informed Consent is attached
   - OR
   - NO.  If NO, answer questions 2 and 3, sign this form, and arrange for an independent physician to complete Section D.

2. Informed consent could not be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.
   - Explain:

3. There was insufficient time to obtain informed consent from the participant's legal representative.
   - Explain why not and what (if any) efforts were made to contact the representative.

4. When was the certification of an independent physician obtained?
   - BEFORE the test article was used
☐ AFTER the test article was used.

If AFTER, how much time elapsed before an independent physician evaluated the use of the article? _______ Hours OR ______ Days

_________________________________________________________    ______________________
Signature of PI       Date

Attach the independent physician’s certification to this form and deliver to IRB within 5 working days.

Section D

Independent Physician Certification: Emergency Use of a Test Article without Informed Consent

I reviewed the use of this test article  BEFORE  AFTER  the use.

I certify that the following statements are true:

☐ The participant was confronted by a life-threatening or severely debilitating situation necessitating the use of this test article.

☐ No alternative method of approved or generally recognized therapy was available that provided an equal or greater likelihood of saving the life the participant.

☐ Informed consent could not be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.

☐ There was insufficient time to obtain consent from the participant’s legal representative.

Name of Independent Physician: ______________________________

__________________________________________________     ___________
Signature of Independent Physician     Date