UCSD Human Research Protection Program Project Review Worksheet
Unplanned Emergency Use of a Test Article

| Section 1: Project Characteristics | | | | | | | |
|---|---|---|---|---|---|---|---|
| HRPP number: | | PI last name | | Reviewer last name | | Date | |
| Project Title: | | | | | | | |

| Section 2: Emergency Use of a Test Article *With* Informed Consent | | |
|---|---|---|
| ***Yes*** | ***No**** | |
| | | The patient has a condition that is life-threatening or severely debilitating. |
| | | No standard acceptable treatment is available. |
| | | There is/was not sufficient time to obtain IRB approval in advance of the use of the test article. |
| | | There is no known available IRB-approved protocol using the same test article or the patient does not qualify for an existing protocol. |
| *(All answers must be "Yes" to qualify for an Emergency Use With Informed Consent)* | | |

*For items checked "No", make an entry in the *Issues Needing Clarification or Revision* section on back

| Section 3: Emergency Use of a Test Article *Without* Informed Consent | | |
|---|---|---|
| ***Yes*** | ***No**** | |
| | | The patient has a condition that is life-threatening or severely debilitating. |
| | | No standard acceptable treatment is available. |
| | | There is/was not sufficient time to obtain IRB approval in advance of the use of the test article. |
| | | There is no known available IRB-approved protocol using the same test article or the patient does not qualify for an existing protocol. |
| | | The patient is confronted by a life-threatening situation necessitating the use of the test article. |
| | | Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the patient. |
| | | Time is not sufficient to obtain consent from the patient's legal representative. |
| | | No alternative method of approved or generally recognized therapy is available that provides an equal or greater than likelihood of saving the patient's life. |
| *(All answers must be "Yes" to qualify for an Emergency Use Without Informed Consent)* | | |

*For items checked "No", make an entry in the *Issues Needing Clarification or Revision* section on back

**Life-threatening** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

**Severely debilitating** means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

| Section 4: Suggested Review Presentation Format | | | | | | | |
|---|---|---|---|---|---|---|---|
| HRPP number: | | PI last name | | Reviewer last name | | Date | |

1. Background and Significance

2. Synopsis of Research Plan

3. Research Plan Issues needing Clarification or Revision

4. Informed Consent Changes Needed

| 5. Overall Recommendation: | | Accept as appropriate Emergency Use | | Do not Accept as appropriate Emergency Use |
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