Banner Health

POLICY and PROCEDURE

TITLE: Emergency Use of Investigational Drug, Biologic, or Device of Off Label Use of Humanitarian Use Device (HUD)			
Number: 3143		**Version: 3143.5**	
Type: Administrative		**Author: Sue Colvin**	
Effective Date: 1/22/2015	**Original Date: 2/21/2005**	**Approval Date: 11/20/2014**	**Deactivation Date:**
Facility: System			
Population (Define): All Employees			
Replaces:			
Approved by: Administrative Policy Committee, Senior Management Team			

TITLE: *Emergency Use of Investigational Drug, Biologic or Device or Off-Label Use of a Humanitarian Use Device (HUD)*

I. Purpose/Expected Outcome:

A. To define the procedures employed by the Banner Health Institutional Review Board (IRB) in situations involving the emergency use of an investigational drug, biologic or device or the off-label use of a Humanitarian Use Device (HUD).

II. Definitions:

A. Compassionate Use – terminology not recognized by either the Food and Drug Administration (FDA) or Department of Health and Human Services (DHHS) and should not be used at Banner Health to describe the emergency use of an investigational drug or biologic.

B. Emergency use – the use of an investigational drug, biologic or device on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.

C. Legally Authorized Representative – and individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

D. Life-threatening Situation – for purposes of section 21 Code of Federal Regulations (CFR) 56.102(d), includes the scope of both life-threatening and severely debilitating defined as follows:
   1. 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 analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death.
   2. 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.

E. Planned Emergency Research – a narrow exception to the FDA's requirement to obtain and document informed consent; applies to a limited class of research activities involving human subjects who are in need of emergency medical intervention but cannot provide legally effective informed consent. This

exception was developed for a particular patient population. This policy does not address planned emergency research.

F. Humanitarian Use Devices (HUD) – a device "intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year."

III. Policy:

A. Emergency situations may arise in which there will be a need to use an investigational drug, biologic or device or the use of an HUD 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, provided, however, the treating physician:
   1. First attempts to contact the IRB Chair or another designated member of the IRB, if within normal business hours, to request approval to proceed with administration of the test article;
   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.

B. If feasible to request prior approval to proceed with administration of the investigation drug, biologic or device (i.e., within normal business hours), the treating physician must provide the following information to the IRB Chair or his/her designee:
   1. Basic clinical information about the proposed use;
   2. Information regarding the status of the emergency Investigational New Drug (IND) or an Investigational Device Exemptions (IDE) that will cover this use (existing protocol, company IND (IDE) or through the FDA directly); and
   3. When possible, a faxed copy of the Informed Consent Form (ICF) to be used.

C. In addition to obtaining the prior approval of the IRB Chair or his/her designee, the subject's informed consent should be obtained. If obtaining informed consent is not possible from the subject or the subject's legally authorized 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 following four conditions are met:
   1. The subject is confronted by a life-threatening situation (as defined above) necessitating the use of the test article;
   2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent, from the subject;
   3. Time is not sufficient to obtain consent from the subject's legally authorized representative; and
   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.

D. 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.

E. The investigational drug, biologic or device 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 panel of the IRB at Banner Health. 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.

F. Physicians may not conclude that an emergency exists in advance of the time when treatment may be needed based solely on the expectation that FDA or Banner IRB approval procedures may require more time than is available. Physicians should exercise reasonable foresight with respect to potential emergencies and make appropriate arrangements far enough in advance to avoid creating a situation where such arrangements are impracticable.

G. Within five working days following the emergency use of the investigational drug, biologic or device, the treating physician shall provide the FDA or the sponsor, whichever is applicable, and the IRB with a written summary of the conditions constituting the emergency, subject protection measures implemented, and the results.

H. 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 the institution that the emergency use was justified and document its' findings. Emergency use reports will be reviewed at the next scheduled meeting, unless the IRB Chair calls a special meeting to review the report.

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

IV. Procedure/Interventions:

A. Prior approval/Notification.
   1. If the emergency use occurs within normal business hours, the treating physician must attempt to contact the applicable IRB Chair to request approval to proceed with administration of the test article.
   2. The following information must be provided to the IRB Chair:
      a. Basic clinical information about the proposed use;
      b. Information regarding the status of the emergency IND (IDE) that will cover this use (existing protocol, company IND (IDE) or through the FDA directly); and
      c. When possible, a faxed copy of the Informed Consent Form to be used.
   3. If the emergency use does not occur within normal business hours, notify the applicable IRB Chair as soon as practicable following the use of the investigational drug, biologic or device.

B. Reporting.
   1. Complete and submit to Banner Research within five (5) business days, a Banner Health Emergency Use Report.
   2. Subsequent use: The treating physician must evaluate the likelihood of a similar need for the emergency use occurring again and if future use is likely, immediately initiate and submit an application to Banner Research.
   3. All emergency use reports will be reviewed by a fully-convened panel of the Banner Health IRB at the next scheduled meeting or at a specially convened meeting if called by the IRB Chair.
   4. IRB acknowledgement of the use will be sent to the treating physician following its review of the emergency use report.

V. Procedural Documentation:

A. N/A

VI. Additional Information:

A. N/A

VII. References:

A. 21 Code of Federal Regulation (CFR) 50
B. 21 CFR 56
C. 21 CFR 59
D. 21 CFR 814

VIII. Other Related Policies/Procedures:

A. ***Policy: Planned Emergency Research (#3124)***
B. ***Policy: Research – Humanitarian Use Devices (#3125)***
C. ***Policy: Research: Investigational Drugs and Biologics (#6065)***
D. ***Policy: Research: Investigational Devices (#6064)***

IX. Cross Index As:

A. Research
B. Emergency Use
C. IRB
D. Compassionate Use

X. Attachments:

A. N/A