KBEMS Pilot Programs- Adverse Event Notification

Emergencies and Reporting of Adverse Events

The responsible project coordinator must promptly notify the Kentucky Board of EMS & the KCTCS HSRB of any problems involving human subjects that arise during the course of the Pilot Program. Problems include unanticipated side effects or adverse reactions from participation in the project and, of course, any injuries. If any emergency occurs during a Pilot Program, you should call 911 and be prepared to provide the following information to the dispatcher: 1) type of injury and what assistance is needed, 2) number of victims, 3) the location and instructions on how to get there, and 4) name and phone number. For research subjects at more than minimal risk, the consent form should include information on available medical treatment if injury should occur and whether any compensation is available for treatment of injuries.

Immediate Cessation of Pilot Programs

All unanticipated side effects and/or adverse reactions must be reported to the KBEMS and KCTCS HSRB. It will be the responsibility of the Pilot Program coordinator to immediately discontinue any Pilot Program in which an adverse effect or injury is associated. It will be within the purview of the Kentucky Board of EMS and the KCTCS HSRB to allow a program to continue after significant review of the details of the incident.

KBEMS Pilot Program Adverse Event Reporting Form

For Unanticipated Problems, Serious or Life-Threatening Events, and related unanticipated Deaths
Kentucky Board of Emergency Medical Services (KBEMS) and KCTCS Human Subjects Review Board (HSRB)

The attached form is to be used ONLY for problems/adverse events occurring under KBEMS & KCTCS HSRB Purview *and*:

All three criteria are true:	1. The problem/adverse event is serious/life-threatening or involving risks to subjects or others; 2. The problem/adverse event was an unanticipated incident; 3. The problem/adverse event is related* to the study procedures.
OR #4 is true:	4. The problem/adverse event involves unanticipated or anticipated **death** which is related* to the study procedures.
OR #5 is true:	5. The problem/adverse event does not fall under the KCTCS HSRB's prompt reporting requirements, but in the **Pilot Program Coordinator's** judgment, prompt reporting of the event(s) is in the best interest of the subject (s) because it may affect the safety and/or welfare of subjects and/or change the risk level of the study.

Reporting Timeframe:

All KBEMS approved Pilot Program problems/adverse events that are serious or life-threatening, AND unanticipated AND which are related* to the study procedures must be reported to KBEMS and the KCTCS HSRB using this form within the following timeframe:

1. Any unanticipated **death** of a subject occurring in a Pilot Program subject that is related* to the study procedures should be reported immediately (i.e. within 48 hours). The Pilot Program shall be discontinued immediately pending review by KBEMS and the KCTCS HSRB.
2. A problem/adverse event experienced by a subject that is **life threatening** and unanticipated, and related* to the study procedures, should be reported within 7 calendar days (1 week) of Pilot Program coordinator's receipt of information.
3. All other **serious** and **unanticipated problems/adverse events** that are related* to study procedures, must be reported within 14 calendar days (2 weeks) of investigator's receipt of information.

KBEMS Pilot Program Adverse Event Reporting Form

Definitions:

- **Unanticipated problem -** any unforeseen or unexpected incident or experience (including an unanticipated adverse event) which is not described in the Pilot Program application or elsewhere in the current application.
- **Unanticipated problem involving risk to subjects or others** - any unforeseen or unexpected event or experience that adversely affects the rights, safety, or welfare of subjects or others (which is not described in the Pilot Program application). The event or experience could involve physical harm/risk (e.g., adverse event), social harm/risk (i.e., inappropriate breach in confidentiality, harm to a subject's reputation, or invasion of privacy), psychological harm/risk or legal harm/risk. The experience could also involve events not previously identified in severity or degree of incidence. An adverse event could be considered an "unanticipated problem involving risk to subjects or others".
- **Anticipated problem/adverse event** – any foreseen or expected incident/experience which was described in the Pilot Program application and approved by KBEMS and the KCTCS HSRB.
- **Serious problem/adverse event** - any incident that results in significant harm to or increased risk for the subject or others. Examples of events which are serious would include but are not limited to, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the subject's health or welfare and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse. A disability is a substantial disruption of a person's ability to conduct normal life functions.
- **Life-threatening event** - any experience that places the subject, in the view of the Pilot Program Coordinator, at *immediate* risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death.
- **Related*** - There is a reasonable possibility, in the opinion of the Pilot Program Coordinator, that the experience was more likely than not to have been caused by the research procedures.
- **PPC**- Abbreviation for Pilot Program Coordinator or Lead investigator.

Complete all applicable items by entering information in the space provided. If items do not apply to your research, insert "N/A" (Not Applicable).

Submit electronically and via hard copy to:

KBEMS
KBEMS Medical Advisor
300 North Main Street
Versailles, KY 40383
kbems@kctcs.edu

AND

KCTCS Human Subject Review Board
Attn: Linda Morefield,
300 North Main Street
Versailles, KY 40383
linda.morefield@kctcs.edu

KBEMS Pilot Program Adverse Event Reporting Form

For Unanticipated Problems, Serious or Life-Threatening Events, and Related Anticipated and Unanticipated Deaths
IRB/IBC

Check the applicable boxes:		
1.	☐	The problem/adverse event is serious/life-threatening or involving risks to subjects or others;
2.	☐	The problem/adverse event was an unanticipated incident;
3.	☐	The problem/adverse event is related* to the study procedures.
4.	☐	The problem/adverse event involves unanticipated or anticipated death which is related* to the study procedures.
5.	☐	The problem/adverse event does not fall under the KCTCS HSRB's prompt reporting requirements, but in the **Pilot Program Coordinator's** judgment, prompt reporting of the event(s) is in the best interest of the subject (s) because it may affect the safety and/or welfare of subjects and/or change the risk level of the study.

ADMINISTRATIVE INFORMATION

Pilot Program Coordinator Name: _____

PPC Telephone Number: _____

PPC E-mail Address: _____

Title of Pilot Program: _____

Name of Pilot Program Site/Organization: _____

Date this report completed: _____

Type of report: Initial Follow-up

Research Participant's study identification number/code: _____ ____N/A

KBEMS Approval Number: _____

HSRB Approval Number: _____ ____N/A

Event Occurred at: _____

Reports submitted to (check all that apply):
____KBEMS
____KCTCS HSRB
____FDA, if applicable
____Sponsor, if applicable

Project is extramurally funded: ____ Yes ____No If yes, list agency(ies)/sponsor(s): _____

Reporter name: _____

Reporter Telephone number: _____

Reporter E-mail address: _____

KBEMS Pilot Program Adverse Event Reporting Form

KBEMS Protocol Number (if applicable): _____ ____N/A

FDA IND Number (if applicable): _____ ____N/A

FDA IDE Number (if applicable): _____ ____N/A

PROTOCOL AND PROBLEM / ADVERSE EVENT (AE) TYPE

____Unanticipated ____ Anticipated and in PPC judgment requires prompt reporting

Seriousness of the Problem/AE (check all that apply):	____Death ____Life-threatening ____Initial or prolonged hospitalization ____Disability ____Congenital anomaly	____ Required intervention to prevent permanent impairment/damage ____ Emotional/Psychological Harm ____ Financial Harm ____ Other medically important condition ____ Non-serious ____ Other
Severity of the Problem/AE	____Mild ____Moderate ____Severe ____Life-Threatening ____Fatal ____N/A	

If death, date of death: / /

Problem/AE Attributed to:	____Study medication ____Underlying disease ____Errors in study medication administration, or deviations ____Breach of Confidentiality ____Device Failure ____Social Science/Education Interventions	____ Concomitant medication ____ Medical Intervention ____Route of administration ____ Invasion of Privacy ____ Other suspected cause (describe on separate sheet) ____ Research Subject Complaint (describe on separate sheet)

Has the same Problem/AE occurred previously in this study? ____Yes ____No If yes, how many times?: _____

SUBJECT DEMOGRAPHICS

Research Participant's gender: ____M ____F

Research Participant's Age in Years: _____

DETAILED UNANTICIPATED PROBLEM/ ADVERSE EVENT INFORMATION

Problem/AE Onset Date: ___/ /_____

Problem/AE Termination Date: ___/ /_____ ____ N/A

____Event Continuing

Description of Event **(include time relationship to investigational procedures):** _____

_____

_____

Action taken in response to Problem/AE: _____

_____

If a subject death, was autopsy performed? ____Yes _____ No _____ N/A

Date of autopsy: / / or ____ N/A

Relevant tests (e.g. x-rays) and results:	____N/A
Describe treatment(s) of Problem/AE (Include medications used to treat this event.)	____N/A
List name of Concomitant Medications (Do not include medications used to treat this event.)	____N/A
Describe pre-existing conditions/relevant clinical history:	____N/A

Date(s) of treatment(s) of the Problem/AE: / / or ____N/A

Outcome of the Problem/AE:	____Recovered/resolved ____Recovering/resolving ____Not recovered/not resolved ____Recovered/resolved with sequelae ____Fatal ____Unknown ____Other _____

Was the administration of the test article stopped because of this Problem/AE? ____Yes _____ No ____N/A

Documentation accompanying the report (e.g., H& P, Progress Notes, Discharge Summary, Lab or Autopsy Reports, Other, etc.):	____N/A
Description of any "other" documentation:	____N/A

SPECIFICATIONS FOR STUDY TEST ARTICLES, IF APPLICABLE

What study test article was administered/received?	____Approved Drug ____ Approved Device _____ IND agent _____ IDE agent _____ Placebo ____ Blinded Study Agent ____N/A ____Other: Describe: _____
Is this Problem/Event a result of a protocol deviation/exception/ violation?	____Yes (If the Problem/Event resulted from an HSRB-approved protocol deviation/exception, provide details on a separate sheet.) ____No

KBEMS Pilot Program Adverse Event Reporting Form

CONSENT/RISK/BENEFIT RATIO

Problem/AE listed in Consent/Assent Form: ____Yes _____ No ____No Approved Form _____ Exempt

Consent/Assent should be revised:	☐ Yes If yes, attach revised form with changes highlighted. ☐ No ____ No Approved Form

Presently enrolled subjects should be informed of Problem/AE: ____Yes _____ No

Risk/Benefit Ratio has changed in light of Problem/AE: ____Yes _____ No

Pilot Program Coordinator Signature: _____ Date _____

Program Medical Director Signature: _____ Date _____

For HSRB Committee Use Only

Section I.

(*Check all that apply*)

🔔 **This** event does **not involve risk to subjects or others** because it is:

- 🔔 not serious/life-threatening
- 🔔 not related to the research
- 🔔 Not unanticipated (i.e., the risk of this event is described in the Pilot Program application).

Or,

- 🔔 Other (*please explain*): _____

[Note: If the event does not involve risk to subjects or others, the HSRB is determining the event **does not** suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized and **does not** warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects. ~*OHRP 1/15/07 Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, III.C.*]

Section II.

(Check one)

🔔 **Report Acknowledged/accepted without recommendation.**

🔔 **Report Acknowledged/accepted pending receipt of additional information to be submitted to the HSRB.**

Comments:

Committee Review Signature_____**Date** _____

J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Unanticipated Problems-Adverse Events\90000-Internal_Reporting_form_final.doc