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| http://chbdt.chboston.org/chbimages/BCHlogo_him.jpg | **SUPPLEMENT Exception from Informed Consent for Emergency Research (EFIC)** |

**Upload this completed form to the Additional Document SmartForm question. To check a box, place an “X” in the box.**

**To answer a text box question, make sure your cursor is in the gray text field before typing or pasting content**

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| **PURPOSE**  |
| The purpose of this application is to provide supplemental information to the IRB about research for which the emergency exception to informed consent is required. This will allow the IRB to determine whether the criteria for approval of the exception are met. The IRB expect that researchers will have read the IRB policy on [Exception from Informed Consent Requirements for](https://www.childrenshospital.org/research/institutional-review-board/guidelines-and-policies)[Emergency Research](https://www.childrenshospital.org/research/institutional-review-board/guidelines-and-policies)  before preparing and submitting this supplement which describe the numerous additional requirements and responsibilities for this type of research. * Additional Information: FDA Guidance “Exception from Informed Consent Requirements for Emergency Research”, April 2013.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf>  |

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| **Study Title:** |       |
| **PI:**  |       |

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| **QUESTIONS** |
| **1. Medical condition being studied.** Describe the medical condition being studied, and why it is considered a life-threatening situation that necessitates urgent intervention.  |
| *“Life-threatening” includes conditions of severe morbidity that are closely associated with mortality. For example, patients with stroke or head injury are at risk of both death and severe disability.*  |
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| **2. Available treatments.** Provide information about the available treatments by answering the questions below. |
| **2.a.** Describe the nature of available treatments for the condition. |
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| **2.b.** Describe how frequently each of the available treatments is used in the geographic location in which you will conduct the study. (“Frequency” refers to approximate percent, not absolute numbers.) |
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| **2.c.** What is it that you consider to be unproven or unsatisfactory about the available treatments?  |
| *“Unproven” means that there is not substantial evidence that a treatment is effective for the condition. This may reflect the absence of any data or the absence of studies of acceptable quality. It includes:** *Treatment that is considered “standard of care” but which has never been subject to rigorous scientific testing or submitted to FDA for approval.*
* *Treatment for which there are no, or insufficient, clinical or pre-clinical data to support safety or efficacy.*
* *A product that is not approved for, nor does the labeling for the product contain, the specific indication or patient population under study.*

*“Unsatisfactory” means that the available product or therapy is effective, but there are drawbacks to its use, such as:** *Safety issues (e.g., high incidence of adverse effects).*
* *Efficacy issues, including:*
* *The time for the treatment to be effective is too long.*
* *The treatment has limitations related to the setting in which it is needed (e.g., should be administered in the field but needs refrigeration; is not portable).*
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| **2.e.** Is there equipoise among the available treatments? If not, why do you think it is important to conduct the study? |
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| **3. Study design**. Provide information about the study design by answering the questions below.  |
| **3.a.** Is this a non-inferiority trial?  |
| *A non-inferiority trial compares a test treatment to a control treatment of established effectiveness and seeks to show that the test treatment is not materially worse than or inferior to the control treatment. It seeks to show that any difference between the two treatments is small enough to allow a conclusion that the test treatment has at least some effect or, in many cases, an effect that is not significantly less than the active control. Non-inferiority trials are generally used in situations where a placebo-controlled trial would be unethical and where there are no data to suggest the new treatment would be more effective than the standard treatment.*  |
|  |  | **No** |  |
|  |  | **Yes** | 🡪 If yes, describe how this study is rigorously designed to show non-inferiority. For example, are there clear data about the effectiveness of the control treatment (to make the non-inferiority study interpretable), and are there known safety or other problems associated with the control treatment that will be measured? Is the sample size sufficient? |
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| **3.b.** Describe other ways that valid scientific evidence could be collected to determine the safety and effectiveness of the intervention. Example: observational data.  |
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| **3.c.** Why is the proposed activity significantly better than the alternative approaches to collecting evidence about the proposed intervention? Be as specific as possible in your answer (i.e., Avoid general statements about the superiority of randomized trials over observational data. Instead, describe specifically what this study would provide that would not be possible or as strong with an alternative approach). |
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| **4. Therapeutic window**. This refers to the time period after onset of the event/condition, based on available scientific evidence, within which the treatment must be administered or used to have its potential clinical effect (diagnostic or therapeutic). For diagnostic devices, it refers to the time period during which diagnosis must occur to allow timely administration of appropriate therapy.  |
| **4.a.** What is the therapeutic window for the treatment(s) you plan to study? Include a description of whether/how the benefit of the treatment changes during the therapeutic window.  |
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| **4.b.** Describe the evidence (e.g., pathophysiologic data, animal data, pre-clinical data) about the duration of the therapeutic window.  |
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| **5. Prospect of direct benefit**. Describe any information from appropriate animal and other preclinical studies that supports the potential for the intervention(s) to provide a direct benefit to the individual subjects. Or, if your study is comparing standard treatments, describe the success rate of each treatment regarding patient morbidity and mortality. |
| *The prospect of direct benefit is not limited to studies evaluating treatment effectiveness. The FDA recognizes that it may be important to obtain preliminary information on dose tolerability or effect on a critical biomarker (e.g., measurement of brain infarcted area, degree and extent of acidosis) before proceeding to a study that evaluates effectiveness. Considered from the point of view of the individual study subject, the FDA has stated that the study intervention could hold out the prospect of direct benefit even if the overall study were not large enough to prove this. For such studies, the UW IRB will rely heavily on the evaluation of the FDA.*  |
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| **6. Justification for exception from consent requirement**. “Consent” means consent from adult subjects, Legally Authorized Representatives, family members for adults who are incapable of providing consent and parental permission for children subjects.  |
| **6.a.** Describe whether this study can be conducted with subjects who can give consent and the results can be generalized to individuals with the same condition who cannot give consent. Provide the rationale for your answer.  |
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| **6.b.** Is it possible to identify in advance the individuals who are risk of the condition that will be treated by the study? |
| *For example: certain types of surgical patients may be at high risk for intra-operative stroke, or certain types of cardiac patients may be at high risk for cardiac arrest.*  |
|  |  | **Yes** | 🡪 If yes, describe how you could identify the individuals, and what proportion of the individuals you would expect to develop the condition you are studying. Describe whether this subject enrollment strategy would make it difficult to conduct the study in a reasonable amount of time, and why. |
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|  |  | **No** | 🡪 If no, provide your rationale. |
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| **6.c.** Why will it not be possible to obtain consent from most subjects, LARs, or family members during the therapeutic window? For approximately what percent of subjects do you expect to be able to obtain consent? |
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| **7. Attempts to obtain consent**. The process you will use for attempting to obtain written consent from the subject (or LAR or family member) should be described in the standard IRB application form. The information requested here is additional information required by the IRB to determine whether this study meets the criteria for granting an exception from the consent requirement.  |
| **7.a.** Consent and the therapeutic window. Describe what portion of the therapeutic window will be devoted to seeking informed consent from a LAR or providing the opportunity for a family member to object to the subject’s participation, including your rationale.  |
| *The FDA does not expect attempts to contact a LAR or family member to exhaust the entire therapeutic window before administering the intervention. The effect of delaying intervention should be taken into account.* |
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| **7.b.** Documentation of attempts to obtain consent. Regulations require the study team to summarize efforts made to contact LARs and family members, and to make this information available to the IRB at the time of continuing review (Status Reports). Describe the method/procedure you will use to document attempts to obtain consent.  |
| *See Question 96 in the* ***FDA’s Guidance: Exception from Informed Consent Requirements for Emergency Research*** *for examples.* |
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| **8. Informing subjects, LARs, family**. Information about the study and the subject’s participation must be provided to the subject, LAR, and/or family member at the earliest feasible opportunity, if consent was not obtained before the study intervention began.  |
| **8.a.** Notification method and content. Describe in detail how you will inform the subject, LAR, and/or family members about the study, what information you will provide, and how this might vary with specific circumstances such as the subject’s death or long-distance LARs/family members.  |
| *See Questions 103 and 104 in the* ***FDA’s Guidance: Exception from Informed Consent Requirements for Emergency Research*** *for expectations about method and contents.*  |
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| **8.b.** Feasibility of notification. The requirement to notify “at the earliest feasible opportunity” incorporates the idea of “practicability”. Describes the situations in which you anticipate it may not be possible to provide information to the subject, LAR or family member.  |
| *Examples: To the subject: if the subject does not survive or is mentally incompetent. To LAR or family member: if the identity of the subject is never determined, or no LAR or family member is known.* |
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| **8.c.** Notification materials. Attach any notification materials to the **Additional Documents** SmartForm question in ***CHeRP***.  |
| *Examples: the consent form, which may be used as an Information Statement; talking points.* |
| **8.d.** Timing of notification. Describe when you will provide notification, and how this might vary with circumstances such as the subject’s death. |
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| **8.e.** Documentation of attempts to notify. Regulations require the study team to summarize efforts made to contact LARs and family members, and to make this information available to the IRB at the time of continuing review (Status Reports). Describe the method/procedure you will use to document attempts to notify |
| *See Question 96 in the* ***FDA’s Guidance: Exception from Informed Consent Requirements for Emergency Research*** *for examples.* |
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| **9. Availability of “opt out”**. Opt out opportunity.  |
| **9.a.** Describe whether and how your study team, first responders, or emergency care personnel will attempt to identify individuals who do not want to participate, even when the individuals are incapacitated and no LAR or family member is available.  |
| *Examples: situations in which it would be reasonably inferred that some incapacitated individuals would not agree to participate in the study such as members of religious groups that object to blood transfusions and other medical interventions; easily accessible sources of information such as a medical identification bracelet or wallet card.* |
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| **9.b.** Will you provide the community in which the research is conducted with an “opt out” mechanism by which individuals can indicate in advance a desire to not participate in this research (or, alternatively, any research involving the exception from informed consent)? |
| *An opt out method is not required by regulations but may be important for building community acceptance and support for the research.* |
|  |  | **No** |  |
|  |  | **Yes** | 🡪 If yes, describe the opt out method you will provide, including how you will notify the community about it. |
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| **10. Community consultation**. Describe how you will obtain community consultation about the study by answering the following questions. ***(NOTE, if a separate Community Consultation plan is submitted as a standalone document or a section of the protocol document you may indicate the name of the document in 10.a and skip to 11. Please ensure the plan includes all relevant information below).*** |
| *Community consultation activities should be designed to help ensure that the communities in which the emergency research will be conducted and from which subjects will be drawn are adequately informed about the risks and expected benefits of the research, and are given the opportunity to ask questions about it and express their views prior to the IRB making a final determination about the study. See Questions 54-77 in the* ***FDA’s Guidance: Exception from Informed Consent Requirements for Emergency Research*** *for guidance and examples.*  |
| **10.a.** Community in which the research will be conducted. Describe the community in which the research will be conducted. |
| *This means the geographic area (e.g., hospital or other facility, or city or region, where the study site is located.* |
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| **10.b.** Describe your community consultation process for the community in which the research will be conducted. Include: the activities; the information that will be provided and how; locations; and who will conduct or be involved in the activities. |
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| **10.c.** Community from which subjects will be drawn. Describe the community from which the subjects will be drawn. |
| *This means the community at risk – in other words, the group of patients who share a particular medical or other characteristic that increases the likelihood that they (or a family member) may be enrolled in the study.* |
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| **10.d.** Describe your community consultation process for the community from which subjects will be drawn. Include: the activities; the information that will be provided and how; locations; and who will conduct or be involved in the activities. |
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| **10.e.** Materials. Attach to the **Additional Documents** SmartForm question in ***CHeRP*** any materials you will use for community consultation. |
| *Examples: flyers, ads, social media posts, newsletter, survey questions, guide for focus groups etc.*  |
| **11. Public disclosure**. Describe how you will meet the requirement for public disclosure by answering the following questions. Note that some activities may be considered both “community consultation” and “public disclosure” activities. ***(NOTE, if a separate Public Disclosure plan is submitted as a standalone document or a section of the protocol document you may indicate the name of the document in 11.a and skip to end of document. Please ensure the plan includes all relevant information below).*** |
| *“Public disclosure” refers to the one-way dissemination of information to the community(ies) and public about the emergency research (1) before the initiation of the study, and (2) after the study is completed or terminated. See Questions 78-94 in the* ***FDA’s Guidance: Exception from Informed Consent Requirements for Emergency Research*** *for guidance and examples.* |
| **11.a.** Describe how you will meet the requirement for public disclosure prior to the initiation of the study. Include: the activities; the information that will be provided and how; locations; who will conduct or be involved in the activities; and which activities/opportunities will continue throughout the study.  |
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| **11.b.** Materials. Attach to the **Additional Documents**  SmartForm question in ***CHeRP***  any materials you will use for public notification. |
| *Examples: flyers, ads, social media posts, newsletter, survey questions, guide for focus groups, etc.*  |
| **11.c.** Describe how you will meet the requirement for public disclosure after the completion or termination of the study. Include: the activities; the information that will be provided and how; locations; and who will conduct or be involved in the activities. |
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