**IRB Member Checklist for Planned Emergency Projects**

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| IRB Meeting Date: Click or tap to enter a date. | eBridge #: Click or tap here to enter text. |
| Principal Investigator:Click or tap here to enter text. | Reviewer: Click or tap here to enter text. |

This checklist should be used with the *New Protocol Reviewer Checklist* for projects which request a waiver of consent for emergency situations (EFIC or planned emergency research). IRB Committee Members should apply the criteria outlined within the *IRB Member SOP: Planned Emergency Research.* **Complete the appropriate sections depending on if the project is or is not subject to FDA regulations.**

Is the Project subject to FDA Regulations (21 CFR 50.24)  Yes  No (if no, complete the [Project not subject to FDA regulations](#_Projects_not_subject) section only). Click to expand the applicable section.

# Projects subject to FDA regulations

1. Is the target population for the research is in a life-threatening situation; available treatments are unproven or unsatisfactory?  Yes  No
2. Is the collection of valid scientific evidence, which may include evidence, obtained through randomized placebo-controlled investigations, necessary to determine the safety and effectiveness of particular interventions?  Yes  No
3. Is the project able to obtain Informed Consent from subjects?  Yes  No
   1. If no, is obtaining informed consent is not feasible because: (check all that apply)

The subjects will not be able to give their informed consent as a result of their medical condition;  
 The intervention under investigation must be administered before consent from the subjects’ legally authorized representatives is feasible; and  
 There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

1. Does participation in the project hold out the prospect of direct benefit to the subjects?  
    Yes  No
   1. If yes, please check all the reasons described in the project:

The subjects are facing a life-threatening situation that necessitates intervention;  
 Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and  
 The risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of the proposed intervention or activity.  Yes  No

1. Can the clinical investigation practicably be carried out without the waiver of consent?  Yes  No
2. Does the proposed project plan defines the length of the potential therapeutic window based on scientific evidence?  Yes  No
3. Has the Investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent?  Yes  No

*The Investigator must agree to summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.*

1. Does the informed consent process and informed consent document meet the federal regulations and IRB policies and procedures (see initial reviewer’s checklist) including the use of legally authorized representatives when feasible?  Yes  No
2. Has the Investigator described the following additional protections of the rights and welfare of the subjects that will be provided, including, at least:  Yes  No
   1. If yes, please check all which have been described in the application:

Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;  
 Prior to the initiation of the clinical investigation, public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn of plans for the investigation and its risks and expected benefits;

At the completion of the clinical investigation there are plans for Public disclosure of sufficient information to apprise the community and researchers of the project. The information must include the demographic characteristics of the research population and results of the clinical investigation.  
 Establishment of an independent data and safety monitoring committee to exercise oversight of the clinical investigation; and  
 If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the Investigator must commit to attempting to contact within the therapeutic window, the subject’s family member who is not a legally authorized representative, and asking whether he/she objects to the subject’s participation in the clinical investigation. The Investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

1. Are procedures in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject’s inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document, specifically that the he/she may discontinue the subject’s participation at any time without penalty or loss of benefits of which the subject is otherwise entitled?  Yes  No
2. If a legally authorized representative or family member is told about the clinical investigation and the subject’s condition improves, does the project include a process to have the subject informed as soon as feasible?  Yes  No

*For the purposes of this waiver “family member” means any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship*

1. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, does the project include a process to have information about the clinical investigation to be provided to the subject’s legally authorized representative or family member, if feasible?  Yes  No
2. Does the project indicate all clinical investigation records, including regulatory files, will be maintained for at least 3 years after the completion of the clinical investigation and will be accessible for inspection and copying by the regulatory authorities, as applicable?  Yes  No
3. Does the project have an investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies that the clinical investigation may include subjects who are unable to consent?  Yes  No

*A submission of these clinical investigations to the FDA for a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for this IND/IDE may not be submitted as an amendment to the existing IND/IDE.*

# Projects not subject to FDA Regulations

1. Is the target population for the research is in a life-threatening situation; available treatments are unproven or unsatisfactory?  Yes  No
2. Is the collection of valid scientific evidence, which may include evidence, obtained through randomized placebo-controlled investigations, necessary to determine the safety and effectiveness of particular interventions?  Yes  No
3. Is the project able to obtain Informed Consent from subjects?  Yes  No
   1. If no, is obtaining informed consent is not feasible because: (check all that apply)

The subjects will not be able to give their informed consent as a result of their medical condition;  
 The intervention under investigation must be administered before consent from the subjects’ legally authorized representatives is feasible; and  
 There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

1. Does participation in the project hold out the prospect of direct benefit to the subjects?  Yes  No
   1. If yes, please check all the reasons described in the project:

Subjects are facing a life-threatening situation that necessitated intervention.

Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence supported the potential for the intervention to provide a direct benefit to the individual subjects.

The risks associated with the research are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

1. Can the research project practicably be carried out without the waiver of consent?  Yes  No
2. Does the proposed project plan defines the length of the potential therapeutic window based on scientific evidence?  Yes  No
3. Has the Investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent?  Yes  No

*The Investigator must agree to summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.*

1. Does the informed consent process and informed consent document meet the federal regulations (45 CFR 46.116 and 46.117) and IRB policies and procedures (see initial reviewer’s checklist) including the use of legally authorized representatives when feasible?  Yes  No
2. Has the investigator provided procedures and information to be used when providing an opportunity for a family member to object to a subject’s participation in the research consistent with this waiver?  Yes  No
3. Has the Investigator described the following additional protections of the rights and welfare of the subjects that will be provided, including, at least:  Yes  No
   1. If yes, please check all which have been described in the application:

Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;  
 Prior to the initiation of the clinical investigation, public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn of plans for the investigation and its risks and expected benefits;

At the completion of the clinical investigation there are plans for Public disclosure of sufficient information to apprise the community and researchers of the project. The information must include the demographic characteristics of the research population and results of the clinical investigation.  
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1. Are procedures in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject’s inclusion in the research, the details of the project and other information contained in the informed consent document, specifically that the he/she may discontinue the subject’s participation at any time without penalty or loss of benefits of which the subject is otherwise entitled?  Yes  No
2. If a legally authorized representative or family member is told about the research and the subject’s condition improves, does the project have a process to inform the subject as soon as feasible?  Yes  No
3. If a subject is entered into research with waived consent and the subject dies before a legally authorized representative or family member can be contacted, does the project have a process to provide information about the research to the subject’s legally authorized representative or family member, if feasible.  Yes  No

*For the purposes of this waiver “family member” means any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.*