1. Federal Regulations (21 CFR 50.24) allow investigators to conduct clinical investigations subject to FDA regulations where obtaining consent from the subject would not be possible prior to the event, providing required conditions are met.
2. Investigators who wish to conduct this type of clinical investigation must submit an eBridge PRO SmartForm for review and approval. The application must describe and satisfy the following identified regulatory requirements set forth by the FDA for this type of clinical investigation.
    a. The target population for the research is in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
    b. Obtaining informed consent is not feasible because:
        i. The subjects will not be able to give their informed consent as a result of their medical condition;
        ii. The intervention under investigation must be administered before consent from the subjects' legally authorized representatives (LAR) is feasible; and
        iii. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
    c. Participation in the research holds out the prospect of direct benefit to the subjects because:
        i. The subjects are facing a life-threatening situation that necessitates intervention;
        ii. 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
        iii. The risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, and what is known about the risks and benefits of the proposed intervention or activity.
    d. The clinical investigation could not practicably be carried out without the waiver.
    e. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the Investigator has committed to attempting to contact a LAR for each subject within that window of time and, if feasible, to asking the LAR contacted for consent within that window rather than proceeding without consent. 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.
    f. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with Federal regulations and IRB policies and procedures. The informed consent procedures and the informed consent document are to be used with subjects or their LAR in situations where use of such procedures and documents is feasible.
    g. Additional protections of the rights and welfare of the subjects will be provided, including, at least:
        i. 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;

Projects not subject to FDA Regulations

1. Federal Regulations (45 CFR 46.101 (i)) allow investigators to conduct research which are not subject to FDA regulations in instances where obtaining consent from the subject would not be possible prior to the event as noted in 61 FR 51531.

2. Investigators who wish to conduct this type of research must submit an eBridge PRO SmartForm for review and approval. The application must describe and satisfy the following identified regulatory requirements set forth by OHRP for this type of investigation.
    a. The research subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
    b. Obtaining consent is not feasible because:
        i. The subjects are not able to give their consent as a result of their medical condition.
        ii. The intervention involved in the research is administered before consent from the subjects' LAR is feasible.
        iii. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.
    c. Participation in the research held out the prospect of direct benefit to the subjects because:
        i. Subjects are facing a life-threatening situation that necessitated intervention.
        ii. 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.
        iii. 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.
    d. The research could not practicably be carried out without the waiver.
    e. The proposed research project defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a LAR for each subject within that window of time and, if feasible, asking the LAR contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact representatives and make this information available to the IRB at the time of continuing review.
    f. The IRB has reviewed and approved consent procedures and a consent document in accord with 45 CFR 46.116 and 46.117.
    g. These procedures and the consent document are to be used with subjects or their LARs in situations where use of such procedures and documented is feasible.
    h. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the research.

i. Additional protections of the rights and welfare of the subjects are provided, including, at least:
    i. Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research is conducted and from which the subjects are drawn.

SUPPORTING DOCUMENTS:
N/A

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