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| **IRB Number** | |  |
| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval (HRP-314) when research involves a waiver of the consent process for planned emergency research. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure) when research involves a waiver of the consent process for planned emergency research.   * For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations and protocol-specific findings justifying those determinations. The Designated Reviewer attaches this checklist n the “Submit Non-Committee Review” activity. The IRB Office retains this checklist in the study file. * For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:  1. The primary IRB Analyst for the convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol-specific findings justifying those determinations, in which case this checklist does not need to be completed or retained. 2. The IRB reviewer(s) for the convened IRB completes this checklist to document determinations required by the regulations along with protocol-specific findings justifying those determinations, and the IRB Office (HRPP/HSPO) uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the study file. | | |
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| 1. Waiver of the Informed Consent Process for Planned Emergency Research (Check if “Yes” or “N/A.” All must be checked.) | | |
|  | The research is **NOT** subject to regulation by a Common Rule agency other than DHHS. | |
|  | The research does **NOT** involve prisoners as participants. | |
|  | The research does **NOT** involve pregnant women, fetuses, non-viable neonates, or neonates of uncertain viability. | |
|  | If the research is **NOT** USFDA-regulated, the research is not subject to regulations codified by the USFDA at title 21 CFR part 50. **(“N/A” if USFDA-regulated) N/A:** | |
|  | If the research involves children as participants, the additional criteria in subpart D of the Common Rule are met, and the study aims to address an important problem in the pediatric population.  *Provide protocol specific findings justifying this determination:* | |
|  | The IRB has reviewed and approved consent procedures and a consent document in accordance with “WORKSHEET: Criteria for Approval (HRP-314).” | |
|  | The Human Participants are in a life-threatening situation.  *Provide protocol specific findings justifying this determination:* | |
|  | Available treatments are unproven or unsatisfactory.  *Provide protocol specific findings justifying this determination:* | |
|  | 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.  *Provide protocol specific findings justifying this determination:* | |
|  | Obtaining informed consent is not feasible because the participants will not be able to give their informed consent as a result of their medical condition.  *Provide protocol specific findings justifying this determination:* | |
|  | Obtaining informed consent is not feasible because the intervention under investigation must be administered before consent from the participants’ legally authorized representatives is feasible. *Provide protocol specific findings justifying this determination:* | |
|  | Obtaining informed consent is not feasible because there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research. *Provide protocol specific findings justifying this determination:* | |
|  | Participation in the research holds out the prospect of direct benefit to the participants because they are facing a life-threatening situation that necessitates intervention.  *Provide protocol specific findings justifying this determination:* | |
|  | 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 participant.  *Provide protocol specific findings justifying this determination:* | |
|  | Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of participants, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity. *Provide protocol specific findings justifying this determination:* | |
|  | The research could not practicably be carried out without the waiver.  *Provide protocol specific findings justifying this determination:* | |
|  | 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 legally authorized representative for each participant 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. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review. *Provide protocol specific findings justifying this determination:* | |
|  | Additional protections of the rights and welfare of the participants will include consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the participants will be drawn. A summary of comments/concerns raised by the community should be presented to the IRB.  *Provide protocol specific findings justifying this determination:* | |
|  | Additional protections of the rights and welfare of the participants will include a plan, including a draft copy, for public disclosure to the communities in which the research will be conducted and from which the participants will be drawn, prior to initiation of the research, of plans for the investigation and its risks and expected benefits. *Provide protocol specific findings justifying this determination:* | |
|  | Additional protections of the rights and welfare of the subjects will include public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results. The PI has provided this plan, including a draft copy.  *Provide protocol specific findings justifying this determination:* | |
|  | Additional protections of the rights and welfare of the subjects will include the establishment of an independent data monitoring committee to exercise oversight of the research.  *Provide protocol specific findings justifying this determination:* | |
|  | If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the participant’s family member who is not a legally authorized representative and ask whether the family member object to the participant’s participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at continuing review.  *Provide protocol specific findings justifying this determination:* | |
|  | Procedures are in place to inform, at the earliest feasible opportunity, each participant, or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, of the participant’s inclusion in the research, the details of the investigation and other information contained in the informed consent document.  *Provide protocol specific findings justifying this determination:* | |
|  | There is a procedure to inform the participant, or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, that the participant may discontinue the participant’s participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. The investigator has provided a plan on how to safely withdraw the participant if the participant or their LAR wishes to withdraw.  *Provide protocol specific findings justifying this determination:* | |
|  | If a legally authorized representative or family member is told about the research and the participant’s condition improves, the participant is also to be informed as soon as feasible.  *Provide protocol specific findings justifying this determination:* | |
|  | If a participant is entered into research with waived consent and the participant dies before a legally authorized representative or family member can be contacted, information about the research is to be provided to the participant’s legally authorized representative or family member, if feasible.  *Provide protocol specific findings justifying this determination:* | |
|  | The investigator will interpret “family member” to mean 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 participant is the equivalent of a family relationship.  *Provide protocol specific findings justifying this determination:* | |
|  | The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a participant’s participation in the research consistent with this waiver.  *Provide protocol specific findings justifying this determination:* | |
|  | If the research is USFDA-regulated, the protocol is being performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies this protocol as including participants who are unable to consent (even if an IND for the same drug product or an IDE for the same device already exists). **(“N/A” if not USFDA-regulated) N/A:** | |
|  | If the research is USFDA-regulated, a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the research has concurred with the above findings. **(“N/A” if not USFDA-regulated) N/A:** | |
|  | If the research is Department of Defense (DOD) regulated, the Secretary of Defense must approve a waiver of the advance informed consent provision of 10 USC 980. **(“N/A” if not DOD-regulated) N/A:** | |
| If an IRB determines that it cannot approve a protocol because it does not meet the criteria in the exception or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly (no longer than within 30 days) in writing to the investigator and the sponsor. | | |