RUTGERS UNIVERSITY
Office for Research

CHECKLIST: Waiver of Consent for Planned Emergency Research

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6.101 (HRP-419)	5/1/2024	1 of 2

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the 4.202 (HRP-314) WORKSHEET: Criteria for Approval when research involves waiver of consent 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.)

- 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 along with protocol-specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol 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 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 convened IRB completes this checklist to document determinations required by the regulations along with protocol-specific findings justifying those determinations, and the Designated Reviewer uploads this checklist in the "Submit Designated Review" activity and retains this checklist in the protocol file.

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 subjects.
☐	The research does **NOT** involve pregnant women, fetuses, non-viable neonates, or neonates of uncertain viability.
☐	The IRB has reviewed and approved consent procedures and a consent document in accordance with 4.202 (HRP-314) - WORKSHEET: Criteria for Approval.
☐	The Human Subjects 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 subjects 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 subjects' Legally Authorized Representative (LAR) 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 subjects 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 subject. *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 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. *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 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 will summarize efforts made to contact LARs 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 subjects 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 subjects will be drawn. *Provide protocol-specific findings justifying this determination:*
☐	Additional protections of the rights and welfare of the subjects will include public disclosure to the communities in which the research will be conducted and from which the subjects 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. *Provide protocol-specific findings justifying this determination:*
☐	Additional protections of the rights and welfare of the subjects will include 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 LAR is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a LAR, and asking whether he or she objects to the subject's participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review. *Provide protocol-specific findings justifying this determination:*
☐	Procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a LAR 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 investigation and other information contained in the informed consent document. *Provide protocol-specific findings justifying this determination:*
☐	There is a procedure to inform the subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. *Provide protocol-specific findings justifying this determination:*
☐	If a LAR or family member is told about the research and the subject's condition improves, the subject is also to be informed as soon as feasible. *Provide protocol-specific findings justifying this determination:*
☐	If a subject is entered into a research with waived consent and the subject dies before a LAR or family member can be contacted, information about the research is to be provided to the subject's LAR 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 subject 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 subject's participation in the research consistent with this waiver. *Provide protocol-specific findings justifying this determination:*
☐	The institution has been notified of the proposed research to verify that the protocol plan complies with applicable State laws.
☐	If the research is FDA-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 subjects who are unable to consent. **("N/A" if not FDA-regulated) N/A:** ☐
☐	If the research is FDA-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 FDA-regulated) N/A:** ☐
☐	If the research is NOT FDA-regulated, the research is not subject to regulations codified by the FDA at title 21 CFR part 50. **("N/A" if FDA-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 in writing to the investigator and the sponsor.	