# WAIVER OF INFORMED CONSENT REQUIREMENTS

# IRB Number:

**Project Title:**

**Principal Investigator:**

**Please check the applicable category of waiver(s) requested:**

**[ ]  Waiver of Informed Consent (waiver of the entire process of informed consent) -complete Section 1.**

**[ ]  Waiver of Required Elements of Informed Consent - complete Section 1 & 2.**

**[ ]  Waiver of Documentation of Informed Consent (waiver of signatures) -complete Section 3.**

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| **Section 1:**  |
| If there is more than one study population (or groups/study arms) in the study, please describe the population(s) (or groups/study arms) for which this wavier pertains:       [ ]  N/A – applies to all research participants.Describe why the research cannot practicably be carried out without the waiver:      Please check either box 1 **or** box 2 below: [ ]  (1) The following criteria are met:* + - * The research involves no more than minimal risk to the research participants;
			* The research could not practicably be carried out without the requested waiver or alteration;
			* If the research involves the use of identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
			* The waiver or alteration will not adversely affect the rights and welfare of the participants;
			* Whenever appropriate, the research participants or LARs will be provided with additional pertinent information after participation (e.g., debriefing research participants involved in deception research).

If box (1) is checked, when applicable, describe how the research participants will be provided with additional pertinent information after participation:       [ ]  N/A[ ]  (2) The research cannot practicably be carried out without the waiver or alteration and the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:* + - public benefit or service programs;
		- procedures for obtaining benefits or services under those programs;
		- possible changes in or alternatives to those programs or procedures; or
		- possible changes in methods or levels of payment for benefits or services under those programs
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| **Section 2:** |
| If there is more than one study population (or groups/study arms) in the study, please describe the population(s) (or groups/study arms) for which this wavier pertains:       [ ]  N/A – applies to all research participants.Check the element(s) of informed consent for which this waiver request applies:[ ]  (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the research participant’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;[ ]  (2) A description of any reasonably foreseeable risks or discomforts to the research participant;[ ]  (3) A description of any benefits to the research participant or to others which may reasonably be expected from the research;[ ]  (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the research participant;[ ]  (5) A statement describing the extent, if any, to which confidentiality of records identifying the research participant will be maintained;[ ]  (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;[ ]  (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the research participant; and[ ]  (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the research participant is otherwise entitled and the research participant may discontinue participation at any time without penalty or loss of benefits to which the research participant is otherwise entitled.Provide a justification for requesting a waiver of the above checked element(s):       |

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| **Section 3:** |
| If there is more than one study population (or groups/study arms) in the study, please describe the population(s) (or groups/study arms) for which this wavier pertains:       [ ]  N/A – applies to all research participants.Provide a detailed explanation for making this request:      Please check either box 1, 2, **or** 3 to describe the criteria that justifies your request for waiver of documentation of informed consent: [ ]  (1) That the research presents no more than minimal risk of harm to research participants and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, survey, collection of quality improvement data, etc.).[ ]  (2) The only record linking the research participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the research participant wants documentation linking him/her with the research and his/her wishes will govern. If box (2) is checked, describe how the study team will link a research participant to the research if the research participant requests such documentation:      [ ]  (3) The research participant (or LAR/surrogate) are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.If box (2) is checked, describe how the study team will document informed consent took place (e.g., making a note on the informed consent document or placing a note in the research record, etc.):     *Caution: Option #3 is only for research approvals on or after 1.21.2019, not regulated by FDA or DOJ.* |