Checklist: Waiver of Documentation of Informed (signed) Consent ([45 CFR 46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117))

Please provide a justification as to how this study meets the applicable criteria for any of the criteria listed below.

|  |  |  |
| --- | --- | --- |
| Select which criteria applies | Criteria | Investigator Response |
|  | That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; | *Type text here, if applicable* |
|  | That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or | *Type text here, if applicable* |
|  | If the subjects or legally authorized representatives 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 subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. | *Type text here, if applicable* |