WAIVER OF WRITTEN DOCUMENTATION OF CONSENT CHECK LIST
Addendum II

(Form date 1/2019)

The Administrative staff will review the Submission Form and any supporting documents related to the protocol to assess whether it qualifies for a Waiver of Documentation of Informed Consent.

The Administrative staff will document their findings on the Check List and file it with the acknowledgement letter to the investigator and the supporting documents in the protocol binder.

The Administrative staff will refer the request to the Chair of the CHS CIRB if a waiver status appears unclear. (Reference: Policy: Waiver of Consent: Waiver or Alteration of Informed Consent and Waiver of Documentation of Consent IRB 13).

Protocol title:
Investigator:

The research must meet one of the following three sets of criteria.

1	**Waiver of written documentation of consent (check if "Yes". All must be checked.)**
☐	The research involves no more than minimal risk to the subjects. *Provide protocol specific findings justifying this determination.*
☐	The research involves no procedures for which written consent Is normally required outside of the research context.
☐	The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure.
	Select one of the following: (One must be checked) ☐Written information describing the research **is to be provided** to the subject or the subject's legally authorized representative (LAR) ☐Written information describing the research **does not need** to be provided to the subject's or the subject's LAR.
2	**Waiver of written documentation (Check if "Yes". All must be checked)**
☐	The research is **NOT** FDA regulated.
☐	The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure.
☐	The only record linking the subject and the research would be the consent document.
☐	The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.

☐	Each subject or LAR will be asked whether the subject wants documentation linking the subject with the research and the subject's decision will govern.
	Select one of the following: (One must be checked) ☐Written information describing the research **is to be provided** to the subject or the subject's legally authorized representative (LAR) ☐Written information describing the research **does not need** to be provided to the subject's or the subject's LAR.
3	**Waiver of documentation of consent (Check if "Yes". All must be checked)**
☐	The research is not FDA regulated.
☐	The research is subject to the 2018 rule.
☐	The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure.
☐	The research involves no more than minimal risk to the subjects. *Provide protocol specific findings justifying this determination.*
☐	The subjects or LAR area members of a distinct cultural group0 or community in which signing forms is not the norm.
☐	There is an appropriate alternative mechanism for documenting that informed consent was obtained.
	Select one of the following: (One must be checked) ☐Written information describing the research **is to be provided** to the subject or the subject's legally authorized representative (LAR) ☐Written information describing the research **does not need** to be provided to the subject's or the subject's LAR.

☐ Waiver of Informed Consent
☐ Refer to CHS CIRB Chair
☐ Refer to full CHS CIRB for review

_____ _____
Signature of Reviewer Date

_____ _____
Signature of Chair (if applicable) Date