WAIVER OF CONSENT CHECK LIST
Addendum I
(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 Informed Consent, Alteration of Informed Consent or 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 (3) sets of criteria.

1	**Waiver or alteration of Consent Process (check if "Yes". All must be checked.)**
☐	The research is **NOT** FDA regulated.
☐	The research does **NOT** involve non-viable neonates.
☐	The research involves no more than minimal risk to the subjects. *Provide protocol specific findings justifying this determination.*
☐	The research could **NOT** be practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination*.
☐	If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format. (N/A if research does not use identifiable private information or biospecimens or if the research is not subject to the 2018 Rule) ☐ N/A
☐	The waiver or alteration will NOT adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination*.
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination*.
☐	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent. (N/A if waiving informed consent, or if the research is not subject to the 2018 Rule) ☐ N/A
2	**Waiver or Alteration of Consent Process (Check if "Yes". All must be checked)**
☐	The research **IS** FDA regulated.

☐	The clinical investigator involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i) to the subjects. *Provide protocol specific findings justifying this determination*.
☐	The waiver or alteration will NOT adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination*.
☐	The research could **NOT** be practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination*.
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination*.
3	**Waiver or Alteration of Consent Process (Check if "Yes". All must be checked)**
☐	The research is **NOT** FDA regulated.
☐	The research does **NOT** involve non-viable neonates.
☐	The research or demonstration projects is to be conducted by or subject to the approval of state or local government officials. *Provide protocol specific findings justifying this determination*
☐	The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: (Check all boxes that are true. One must be checked) ☐Public benefit or service programs. ☐Procedures for obtaining benefits or services under those programs. ☐Possible changes in or alternatives to those programs or procedures. ☐Possible changes in methods or levels of payment for benefits or servies under those programs. *Provide protocol specific findings justifying this determination*
☐	The research could **NOT** be practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination*.
☐	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent. (N/A if waiving informed consent, or if the research is not subject to the 2018 Rule) ☐ N/A

☐ 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