

Checklist for Research Involving Neonates

Principal Investigator (Last, First):

Protocol # (XX-XX-XXXX):

Project Title:

1. Is the neonate viable?

Yes No

(If "Yes," use checklist for children)

2. Is the neonate of uncertain viability?

Yes No

**If Yes,
Requirement #1:**

Does the research hold out the prospect of enhancing the probability of survival to the point of viability, and is any risk the least possible for achieving that objective?

Yes No

OR

Is the purpose of the research the development of important biomedical knowledge which cannot be obtained by other means and will there be no added risk to the neonate?

Yes No

Requirement #2:

Has informed consent been obtained from either parent or either parent's legally authorized representative (if parents are unable?)

Yes No

3. Is the neonate non-viable?

Yes No

If "Yes,"

Will the vital functions of the infant not be artificially maintained?

Yes No

Will the research not terminate the heartbeat or respiration?

Yes No

Will there be no added risk to the neonate?

Yes No

Will the purpose of the research be the development of important biomedical knowledge that cannot be obtained by other means?

Yes No

Has the legally effective informed consent been obtained from both parents or, if one parent is unable to provide consent, from the other parent?

Yes No