**CHECKLIST: Documentation of Waiver Approval**

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The purpose of this checklist is to provide documentation of waiver approval for Designated Reviewers conducting Non-Committee Review. This checklist is to be completed by the Designated Reviewer, signed, dated, and retained.

**IRB Number:**

**Protocol Name:**

**Investigator:**

1. **REVIEWER CRITERIA** *(Check if “Yes.” All must be checked)*
   - I do not have a Conflicting Interest.

2. **DOCUMENTATION OF WAIVER APPROVAL** *(Check if “Yes”. All must be checked)*
   - (i) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: *(Check if “Yes”. All must be checked)*
     - a. An adequate plan to protect the identifiers from improper use and disclosure.
     - Provide protocol specific findings justifying this determination:
     - b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
     - Provide protocol specific findings justifying this determination:
     - c. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.
     - Provide protocol specific findings justifying this determination:
   - (ii) The research could **NOT** practicably be conducted without the waiver or alteration.
   - Provide protocol specific findings justifying this determination:
   - (iii) The research could **NOT** practicably be conducted without access to and use of the protected health information.
   - Provide protocol specific findings justifying this determination:
   - (iv) A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board as provided in section (iii) above.
   - Provide protocol specific findings justifying this determination:
   - (v) The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects.
   - Provide protocol specific findings justifying this determination:
   - (vi) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
   - Provide protocol specific findings justifying this determination:

**Comments:**

The IRB has reviewed and approved the waiver of individual authorization under expedited review procedures consistent with the requirements under the Common Rule and other applicable regulations.

**Attach required Approval of Human Research Letter**

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<tr>
<th>Reviewer Signature:</th>
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