# CHECKLIST: Waiver of Documentation of Consent

This checklist is used to determine whether written documentation of the consent process can be waived for non-exempt Human Research.

## Criteria

All criteria in 1 or 2 must be met

### 1. Waiver of written documentation of consent for research involving Minimal Risk to subjects

- **1.1** The research presents no more than Minimal Risk to subjects
- **1.2** The research involves no procedures for which written consent is normally required outside of the research context
- **1.3** The investigator will provide a written statement regarding the research that embodies the elements of consent in Section 4 of "WORKSHEET: Criteria for Approval (HRP-400)" (see Footnote 1)
  - One of the following is true:
    - The investigator will provide subjects with that written statement
    - The investigator will not provide subjects with that written statement but will read it to the subjects

### 2. Waiver of written documentation of consent for confidentiality risk

- **2.1** The only record linking the subject and the research will be the consent document
- **2.2** The principal risk is potential harm resulting from a breach of confidentiality
- **2.3** Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern (see Footnote 2)
- **2.4** The research is not FDA-regulated
- **2.5** The investigator will provide a written statement regarding the research that embodies the elements of consent in Section 4 of "WORKSHEET: Criteria for Approval (HRP-400)" (see Footnote 1)
  - One of the following is true:
    - The investigator will provide subjects with that written statement
    - The investigator will not provide subjects with that written statement but will read it to the subjects

### Notes

### Footnotes

- **4.1** In general, this is a long form consent document without a signature block
- **4.2** In general, this is a notation by the research staff in the research records and does not need to be a signed consent document