**Worksheet for Waiver of Documentation of Consent[[1]](#footnote-1)**

To be filled out by researcher or analyst, and made part of the eIRB study application

**Study Number**: Click or tap here to enter text.

**PI Name: Christopher Beck, PhD**

**Mode of Review (IRB Use Only):** [ ] Expedited [ ] Full Board

*Also known as “waiver of signature” or “verbal (oral) consent,” and often used for in-person sensitive research, and online surveys. If this waiver is granted for a verbal consent process, the IRB may require the investigator to also provide subjects with an Information Sheet containing most of the elements of a consent form but formatted appropriately (e.g., without signature lines, entitled “Information About the Study”) and a Script for Oral Consent reflecting the investigator’s side of the dialogue. Our consent template can be found at* [*http://www.irb.emory.edu/documents/Verbal\_ConsentHIPAA\_Template.doc*](http://www.irb.emory.edu/documents/Verbal_ConsentHIPAA_Template.doc)

Information Sheet Submitted? [x]  Yes [ ] No

Script for Oral Consent Submitted? [ ] Yes [x]  No

**Options #1 and #2 are available.** Criteria must be met for waiver to be granted. “Documentation” can mean signature or making one’s mark.

*If being completed by Study Team: Please fill in “Protocol-Specific Comments”*

**OPTION #1** (45 CFR 46.117(c)(1)

*Note: Option 1 not applicable to FDA-regulated studies; see Option 2 instead. If the subject prefers having their research information link to their medical record, investigators should follow suit.*

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if the IRB finds that:

[ ] The only record linking the subject and the research would be the consent document AND

[ ] The principal risk of the research would be potential harm resulting from a breach of confidentiality

**(IRB Use Only)** Is the study team required to provide participants with a written statement about the research (e.g., per the Sponsor or because of GCP)? [ ] Yes [ ]  No

Protocol-specific comments: Click or tap here to enter text.

**OR**

**OPTION #2** (45 CFR 46.117(c)(2) and 21 CFR 56.109(c)(1))

[x] The research presents no more than minimal risk of harm to subjects

[x] The research involves no procedures for which written consent is normally required outside of the research context.

Protocol-specific comments: Click or tap here to enter text.

1. 45 CFR 46.117 (c); FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects [↑](#footnote-ref-1)