**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?  Yes No

Script for Oral Consent Submitted? Yes  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))

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

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)