Phoebe

Request for Waiver of Written Documentation of Consent

NOTE: This waiver does not apply to FDA-regulated research.

Principal Investigator:

Study Title:

PI Address:

PI Telephone / Email:

Date of Submission:

Explain why you are asking for a Waiver of Written Documentation of Consent

Typical reasons may include: illiterate participants, cultural constraints against written signature, the only record linking the participant to the research is the consent document, and principal risk would be harm from breach of confidentiality.

Explain how, in the absence of signed written consent forms, consent will be documented
(e.g., tape recorded consent, interview notes, etc.)

Please attach a script of what you will be telling participants when you ask for their consent. This script should cover the same major points that would be in an informed consent document (e.g.; description of research and procedures, expected duration of the participation, disclosure of risks and benefits, how you will keep information confidential, statement that participation is voluntary, contact information).

Waiver of Written Documentation of Consent Category

Research that includes waiver of written documentation of consent should fulfill one of the following. Please mark the appropriate category. Your answer to Question 1 should explain why this is appropriate.

> The research involves no more than minimal risk; and involves only procedures that do not require written consent outside of research.

> The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

Principal Investigator Acknowledgement

P.I.'s Name: _____ Date: _____

Electronic Signature:

Facility Advisor Acknowledgement

Facility Advisor's Name: _____ Date: _____

Electronic Signature:

> *Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" to the left or at top of page.*