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| **or-logo-stacked** | | **Institutional Review Board**  **Human Research Protections**  **Appendix P – Waiver of Signed Consent**  *Version January 2019* | |
| **Researchers:**   * **Please complete Appendix P if you are requesting a waiver of documentation (signed) informed consent** [i.e. to obtain verbal consent obtained with a Study Info Sheet]. * In order for the IRB to grant the waiver, the research must meet one of the three OPTIONS below (i.e. A, B, or C)**.** Skip the options that do not apply. * Please read the [HRPP webpage](http://www.research.uci.edu/compliance/human-research-protections/researchers/drafting-consent-form.html#waiver2) for information about a waiver or alteration of the informed consent. | | | |
| **Lead Researcher/Investigator Name: Jacob Kodner** | | | **HS#: 2020-5968**  ***(to be completed by the IRB)*** |
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| OPTION A: The only record linking the subject and the research would be the informed consent form  and the principal risk would be potential harm resulting from a breach of confidentiality[[1]](#footnote-2)  All of the following criteria must be true. Provide the requisite protocol specific justifications. | | | |
| TRUE | The only document linking the subject and the research would be the signed consent form. | | |
| TRUE | The subject will be provided with a Study Information Sheet or other document that addresses the basic elements of informed consent. | | |
| TRUE | Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. | | |
|  | *Explain why the primary risk of the research is the harm from a possible breach of confidentiality:* | | |
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| **OPTION B (\*Most Common\*):** The research presents no more than minimal risk of harm to subjects  and involves no procedures for which written consent is normally required outside of the research  context[[2]](#footnote-3)  All of the following criteria must be true. Provide the requisite protocol specific justifications. | | | |
| TRUE | The subject will be provided with a Study Information Sheet or other document that addresses the basic elements of informed consent. | | |
| TRUE | If Protected Health Information (PHI) is to be used, created, or disclosed as part of the research study, information on what PHI will be collected, with whom it will be shared, how it will be kept confidential, and when it will be destroyed must be conveyed to the participant unless a Waiver of HIPAA Authorization (i.e., Appendix T) is granted by the IRB. | | |
|  | The research involves no more than [Minimal Risk](https://research.uci.edu/compliance/human-research-protections/irb-members/assessing-risks-and-benefits.html#definitions); [45 CFR 46.116(f)(3)(i)]  *Provide protocol specific justification for this determination:*This study would have qualified to be an Exempt (3.i.A) study, but as a result of including children for the completion of translation tasks, this study falls under Expedited Review Category 6. | | |
|  | *Provide protocol specific justification for why the research procedures would not normally require a signed consent form outside the research environment:*  The protocol involves actions that people regularly perform, including reading a story and providing a translation. Given the bilingual nature of the participants’ families, translating between Sqiliq Atayal and Mandarin is additionally part of their daily life that would not require signing a consent form. | | |
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| **OPTION C:** The subjects or legally authorized representatives are members of a distinct cultural  group or community in which signing forms is not the norm, the research presents no more than  minimal risk of harm to subjects, and there is an appropriate alternative mechanism documenting  that informed consent was obtained[[3]](#footnote-4)  All of the following criteria must be true. Provide the requisite protocol specific justifications. | | | |
| TRUE | The subject will be provided with a Study Information Sheet or other document that addresses the basic elements of informed consent. | | |
|  | *Specify the distinct cultural group or community and explain why signing forms is not the norm:* | | |
|  | The research involves no more than [Minimal Risk](https://research.uci.edu/compliance/human-research-protections/irb-members/assessing-risks-and-benefits.html#definitions); [45 CFR 46.116(f)(3)(i)]  *Provide protocol specific justification for this determination:* | | |
|  | *Specify the alternative mechanism for documenting that informed consent was obtained:* | | |

1. 45 CFR 45.117(c)(1)(i) [↑](#footnote-ref-2)
2. 45 CFR §46.117(c)(1)(ii) [↑](#footnote-ref-3)
3. 45 CFR §46.117(c)(1)(iii) [↑](#footnote-ref-4)