**Waiver of Informed Consent:**

\_\_ Unless this protocol has asked for waiver, we expect **signed** written consent forms.  An oral consent procedure is possible if researchers provides sufficient reasons. (Note that an application falling into the Exempt category is NOT a reason to waive written consent, according to our local IRB norms). The following is a table that indicates when a waiver for paper-signed consent forms could be granted under **45 CFR Part §46.117(c). IRB** reviewers should consider the justifications of the waiver request and determine to grant the waiver to signed consent or not:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Forms of consent** | **Participants’ consent identity known?** | **Waiver for signed consent needed?** |
| **None** | **1.  No consent al all** | **No** | **Yes, waiver justification required.** |
| **Oral** | **2. Oral-recorded** | **Yes** | **No need for waiver if recorded with audio/video.** |
| **3. Oral-not recorded** | **No** | **Yes, waiver justification required.** |
| **Written** | **4. Electronic** | **No (e.g., anonymous online surveys)** | **Usually this would be a “determined exempt review,” so there is no need for requesting a waiver for signed consent. Exception would be that this is not an exempt review.** |
| **5. Electronic** | **Yes (e.g., electronic signature kept in an electronic file)** | **For a full board and expedited review, there is still a need to justify a waiver for signed consent on paper and ink. For an exempt review, no waiver request is needed.** |
| **6. Paper- not signed (e.g., information sheet)** | **No** | **Yes, a waiver is needed.** |
| **7. Paper- signed consent forms** | **Yes** | **No waiver is needed.** |

\_\_ Statements on the consent form are clear and understandable to the participants, considering their cultural backgrounds, educational levels, age, and other social factors important for comprehension. A general recommendation is that consent statements should be understood by 8th graders, but other standards may be appropriate depending on the sample.

\_\_ When applicable, translation of the consent form/script has been provided in this protocol. (Note that our IRB has a Spanish-language consultant to check translation. Please let our Compliance Officer know if there is such a need to call in the consultant.)

\_\_ Contents on the consent form are consistent with the earlier sections 6, 7, and 8.

\_\_ We recommend participants to use the template for consent forms posted on our CSUSB IRB website: <https://www.csusb.edu/institutional-review-board/irb-review/forms-and-templates>  . However, strictly following the template is not a requirement.  Yet, we expect the consent form to include ALL elements laid out in the template.

\_\_ On the consent form, there is a sentence stating that the project has been approved by CSUSB IRB (could also add with some explanations about what IRB is).

\_\_ The consent form has listed the contact email address and office phone numbers of the PI (and co-investigators, if applicable).

\_\_\_ At the end of the consent form, there is a check box or signature space for respondents to provide affirmative consent. This should NOT be an opt-out process.

\_\_When applicable, separate consent for audio and/or video recording should be there.

\_\_ Generally, we should avoid a long and confusing consent form that would potentially obscure important elements of a research.

\_\_ Compensation should be listed under its own subheading in the informed consent and not listed as a benefit.