If you will enroll participants who cannot sign the consent form because they are unable to read or write, are visually impaired, and/or have physical limitations, use the additional signature page “Consent for study participants who are unable to read or write, are visually impaired, and/or have physical limitations that prevent them from signing the consent form on their own behalf”.

**You must receive IRB approval to use this signature page for your study.** In your submission to the IRB, include the reason for adding the signature page and how it will be used in the consenting process. This information should be included in Section 15.1 of your eIRB application\*. You should also a) revise the protocol or other study materials to explain how study procedures may be modified for these participants (e.g. how surveys will be completed), if applicable and b) modify any study-related materials to account for any accommodations that will be made.

The signature page will be stamped upon approval.

* If multiple participants in your study are likely to need this signature page, add it to your consent form and upload the consent form in eIRB Section 15.3.
* If only 1 participant needs the signature page, you may have the page approved as an addendum but do not need to add it to your consent form. The signature page should be uploaded in eIRB Section 15.3 when you request IRB approval of the signature page.

The potential participant must be given the option of having a representative/advocate/friend present during the consent process. This person is called the “authorized representative” for purposes of the consenting process. If the potential participant declines to select their own representative, that is fine; they just need to be given the opportunity.

If the participant does not select a representative, then an impartial witness must attend the informed consent process. The witness can be anyone who is not on the study team and can confirm that the participant has given their fully informed consent.

Either the representative selected by the participant or an impartial witness identified by the study team will need to sign the consent form.

The participant should communicate his/her agreement to participate in the study by making his/her mark on the main signature page, by verbally agreeing, or by some other means (e.g. nodding or blinking). If the participant agrees to the study verbally or by nodding or blinking, the authorized representative or impartial witness should check the box on the separate signature page indicating this was how the consent was communicated.

The consent process must be carefully documented in the research record (i.e. that the potential participant was asked if an advocate/representative/friend should be included, whether someone was selected, who served as the advocate/representative/friend or as the witness).

**\*Sample language for eIRB Section 15.1:**

We will use the Signature Page for Participants Who Cannot Sign the Consent Form for ***<<a participant/ multiple participants>>*** who ***<<explain reason for using the form, e.g. cannot read>>***. The participant will be asked if they have a representative/friend to act as an authorized representative to observe the consent process and sign the consent form, and if not, an impartial witness who is not on the study team will be used. The consent process will be documented in the research record. ***<<Add any specific accommodations that will be used>>***