

Consent Process Examples
Opt-Out Parental Permission for Children's Participation
In Research Conducted at an Elementary School

A Waiver of Documentation of Consent must be approved by the IRB in order to use this consent process model. The Waiver of Documentation of Consent can be requested in the New Study Application, Consent Process page, question 8.

- 1. Provide the parent(s) with all of the required information about the study.**
 - a. Ensure the consent document states that the child will participate in the research unless the parent contacts the school or researcher to opt-out. Provide reliable contact information in the document.
 - b. Because this process uses an opt-out model, use a consent document without a signature block. It is suggested that the Consent Cover Letter Template be used, found on the [Forms and Templates](#) webpage.
 - c. Send a copy of the consent document to the parent(s) in a manner that is appropriate for the school and ensures a high likelihood that the parent(s) will receive the information. This may be via email, mail, or at an in-person parent meeting at the school. It may or may not be appropriate to send the information home with the child, depending on the likelihood that the information will actually be given to the parent(s). Consult with the school for the best method of communication.
- 2. Give information in a language the parent(s) understands.**
 - a. Secure translation of the consent document and other information given to parents, if needed.
- 3. Give the parent(s) an opportunity to ask questions before providing consent.**
 - a. If the parent has questions about the study, the study team should ensure an appropriate individual is available to answer those questions. This may or may not be a person employed by the school. If a school employee will act as a liaison between parents and the study team, ensure this person is well informed to appropriately handle questions and concerns, involving the study team when necessary.
- 4. Give the parent(s) enough time to consider being in the study.**
 - a. Ensure the parents have enough time after receiving the consent document to read it and make contact to opt-out before the study procedures begin.
- 5. Do not use exculpatory language in the consent process.**
- 6. Document that parent(s) consent was obtained before beginning study procedures.**
 - a. Keep written documentation of all children whose parents have opted-out of study participation, including the date that the opt-out request was received.

Ensure that these children are not included in the study procedures. This may require that a separate, non-research activity be made available to them while other children complete study procedures.

7. Give a copy of the signed consent form to the participant.

- a. Because this process uses an opt-out model, a signature will not be obtained. Thus, this element is not required.