

Consent Process Examples
Parental Notification/Opt-Out for Children's Participation
in Research Conducted at School

Description: Based on the nature of a research project and according to the preferences of an individual school or school district, it may be acceptable to notify parents of research conducted at an elementary or secondary school and use an opt-out model if a parent wishes to have their child excluded from the study. An opt-out model may be used only if the IRB has waived the requirement for parental permission. Then, parents are notified about the research and given the option to exclude their child from the research. This example illustrates the steps a study team might take to use a parental notification/opt-out model. ***The IRB must first approve a research proposal and waive parental permission. The Waiver of Consent can be requested in the New Study Application, Study Information page, question 5. The parental notification letter should be attached to the Documents and Attachments page under Parental Permission Forms.***

1. **Provide the parent(s) with all the required information about the study in a language the parent(s) understand.**
 - a. Ensure the parental notification letter states that the child will participate in the research unless the parent contacts the school or researcher to opt-out. Also note that the child may choose not to participate in the research. If a parent or child chooses to opt-out, include a description of any separate, non-research activities that will be made available to them while other students complete the study procedures. Provide reliable contact information in the document.
 - b. Send a copy of the parental notification letter 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 the parent(s) an opportunity to ask questions before the research begins.** If the parent has questions about the study, the study team should ensure an appropriate individual is available to answer those questions. If a school employee provides information about the research study (including the parental notification) to parents, ensure the employee will defer questions and concerns to the study team as necessary.
3. **Give the parent(s) enough time to consider being in the study.** 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. Provide clear instructions detailing how parents should inform the researchers that they do not want their child to participate in the research.
4. **Document instances of parent(s) or children who have opted-out of study procedures.** Keep written documentation of all children or parents who have opted-out of study participation, including the date that the opt-out request was received. Ensure that children who have opted-out or children whose parents opted-out are not included in the study procedures.