

Parent/Guardian Permission for Studies involving Children

When a proposed study involves children, the IRB must consider regulatory requirements that provide additional protections for child research participants. Under these regulations, children are persons who have not attained the legal age for consent under the law of the jurisdiction in which the research is conducted (in the United States, any person under 18). Consent for a child to participate in research is usually a two-stage process. Unless waived by the IRB, the first step is obtaining written consent from the child's parents or legal guardians. This parental consent must be obtained before the researcher can proceed to the second step – seeking the child's agreement to take part in research. Though child assent is a key part of the process, this guidance focuses only on parental consent. For general guidance on research with children, read [IRB SOP 11](#).

Active (opt-in) parental consent

Active (opt-in) consent is typically required before conducting research with human participants. In most cases, parents or legal guardians must affirmatively communicate their approval before their child may participate in research. If you plan to use opt-in consent, follow the general guidelines for informed consent in [IRB SOP 10](#).

Passive (opt-out) parental consent

In limited cases, the IRB may allow an opt-out consent process, where a parent or guardian's consent is assumed unless they communicate otherwise. This is limited to cases where all of the following are true: (1) the study poses no risk; (2) the research cannot practicably be carried out otherwise; and (3) the IRB agrees that opt-out consent is appropriate under the circumstances. If research is conducted in a school setting, the school must agree that an opt-out model is consistent with their internal policies. Additional considerations:

1. **Justify waiver of active consent:** Since active consent is expected, you must justify your use of opt-out consent as necessary and ethically appropriate. The IRB will want to know: if the research is part of regular classroom activities; the expected duration of the children's participation; whether the research could pose any risk, such as sensitive questions that may upset or embarrass; and whether identifying information will be collected.
2. **Document school approval:** For research in schools, include in your IRB application a letter of support for using opt-out consent, signed by the principal or another senior administrator.
3. **Develop a robust plan for informing parents:** Inform parents/guardians about the study and give them an opportunity to state that they do not want their child to participate. Ensuring that information is actually received can be a challenge -- a flyer sent home may never make it there. Therefore, use more than one method to contact parents/guardians, if possible.
4. **Make it easy to opt out:** Similarly, the IRB recommends providing multiple ways for a parent/guardian to inform the researcher that they do not want their child to participate.
5. **Build in sufficient time:** Make sure to give sufficient time for parents/guardians to review the information and act (at least a week), and include a due date for responses.
6. **Set the right tone:** Be helpful and respectful in your communications. Describe the study activities clearly and in detail. A sample opt-out information sheet is provided on the next page.
7. **Have a plan to address concerns:** If a parent/guardian expresses a concern you should address it immediately, beginning by informing the IRB office.
8. **Consider non-English speakers:** In situations where the researcher expects that a substantial number of parents/guardians are illiterate or do not read English, offer an appropriate alternative method of communicating information about the study.

The format of this example opt-out information sheet is appropriate for most studies, but you should adapt it so that it is appropriate for your research and delete any language that does not apply.

Sample Parental Notification Form Regarding Participation in a Research Study

Principal Investigator: Jack Sprat

Faculty Advisor: Tempeh Kohlrabi

Study Title: Assessing K-12 Healthy Eating Curriculums in Apple Valley Public Schools

Dear Parents and Guardians,

I am a Ph.D. candidate at Cornell University. I am conducting a research study of elementary school children to assess their knowledge of and feelings about healthy eating. Honeycrisp Elementary School is familiar with and has given me permission to conduct this research at the school, and is facilitating this communication to you to tell you about the study and give you an opportunity to decide that you do not want your child to participate, if that is your preference.

If you allow your child to participate, we will ask them to complete two short surveys-- one in October and one in May. Both surveys contain identical questions about your child's eating habits, and ask their gender and grade. Each survey will take no more than 10 minutes, and students will not miss any instruction time in order to participate. If a child indicates at any time that they do not want to participate, they will be thanked and will return to their classwork.

There are no known risks to your child from participating in this study. Their grades and class standing will not be affected in any way if they do, or do not, participate. Your child will not directly benefit from this research, however their participation may benefit others by informing development of future instructional materials and processes designed to instill healthy eating habits at a young age.

This research is anonymous. No names or other identifying information will be collected. If a report of this study is published or presented at a professional conference, only group results will be communicated and not individual responses.

The research team is happy to answer any questions you have about the study. Please contact Jack Sprat at 123abc@cornell.edu, or 123-456-7890. If you wish to share a concern or complaint, please contact the Cornell Institutional Review Board for Human Participants (IRB) at irbhp@cornell.edu, or 607-255-5138. You can also report anonymously through Ethicspoint at www.hotline.cornell.edu, or by calling 1-866-293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.

If you do want your child to participate, no further action is necessary. If you do not wish your child to participate, please fill out and sign the form below and return it to your child's homeroom teacher or to Principal Buttersworth. Alternatively, you can send an email to the researchers with the subject line "Opt Out", and include your name and your child's name in the message. Please return the form on the next page or reply via email by September 30. Thank you!

Sample Parental Notification Form Regarding Participation in a Research Study

If you wish to allow your child to participate, please do not return this form – no action is necessary.

If you do not allow your child to take part in the study, do one of the following by September 30:
(1) sign and return this form to your child’s homeroom teacher or Principal Buttersworth (2) email 123abc@cornell.edu with the subject line “Opt Out”, and include your name and your child’s name in the message.

Principal Investigator: Jack Sprat
Faculty Advisor: Tempeh Kohlrabi
Study Title: Assessing K-12 Healthy Eating Curriculums in Apple Valley Public Schools

Notification of Refusal:

I DO NOT give permission for my child to participate in the study described above.

Print Child’s Name

Parent/Guardian’s Signature

Print Parent/Guardian’s Name

Date