# TC IRB Guidance for Researchers: Waiver of Parental/Guardian Consent in Educational Settings

**Purpose**

This guidance is designed to help researchers understand and navigate the complexities of obtaining and using a waiver of parental/guardian consent. It aims to provide clarity on when and how passive consent might be appropriately sought and the **stringent conditions** under which it may be approved.

**Understanding Passive Parental Consent**

Unless waived by the TC IRB, all research involving minors requires **both** the informed written consent of a parent/guardian and the suitably documented assent of the child, if the child is over 7 years old.

Waiver of Parental/Guardian Consent, also colloquially referred to as passive parental/guardian consent or "opt-out consent," is a method that can be considered by the TC IRB under certain justifiable conditions, subject to waiver or alteration of standard informed consent requirements.

**Institutional Review Board Requirements**

In limited cases, TC IRB may allow waiver of consent if a study meets the conditions for a waiver or alteration of informed consent. The a waiver of parental/guardian consent procedure may be used in school settings where the following conditions are met ([45 CFR 46.116(f)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116)):

* The research involves no more than minimal risk to the subjects;
* The waiver or alteration will not adversely affect the rights and welfare of the subjects;
* The research could not practicably be carried out without the waiver or alteration;
* If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and
* Whenever appropriate, the subjects and parents will be provided with additional pertinent information after participation.

The researcher must explain and justify the reasons why the waiver or alteration of informed consent is essential to the study. Inconvenience and expense are not acceptable factors in determining "practicability."

As such waiver or alteration of informed consent approvals are rare, researchers should expect longer timelines and frequent interactions with the TC IRB staff.

**Compliance with Additional Federal Regulations**

*FERPA Compliance*

Family Educational Rights and Privacy Act (FERPA) requires that consent for disclosure of education records be signed and dated, specify the records that may be disclosed, state the purpose of the disclosure, and identify the party or class of parties to whom the disclosure may be made. As such, passive parental consent for disclosure of information from education records would not meet FERPA’s consent requirements.

*PPRA Compliance*

The Protection of Pupil Rights Amendment (PPRA) applies to the programs and activities of a state education agency (SEA), local education agency (LEA), or other recipient of funds under any program funded by the U.S. Department of Education. It governs the administration to students of a survey, analysis, or evaluation that concerns one or more of the following eight protected areas:

1. political affiliations or beliefs of the student or the student’s parent;
2. mental or psychological problems of the student or the student’s family;
3. sex behavior or attitudes;
4. illegal, anti-social, self-incriminating, or demeaning behavior;
5. critical appraisals of other individuals with whom respondents have close family relationships;
6. legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
7. religious practices, affiliations, or beliefs of the student or student’s parent; or
8. income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

PPRA also concerns marketing surveys and other areas of student privacy, parental access to information, and the administration of certain physical examinations to minors. The rights under PPRA transfer from the parents to a student who is 18 years old or an emancipated minor under state law.

To assure PPRA compliance and reduce the risk of inadvertently surveying a child without parental permission, we recommend the following:

* Stress that survey participation is voluntary in all communications. This is a key requirement for the use of passive consent procedures in the PPRA. Notify students in writing and verbally (before survey administration) that they have the right to decline participation and to not answer any question that makes them uncomfortable. Make sure nothing is done that might cause a student to feel uncomfortable if he doesn’t want to participate.
* Send all consent information and forms via a method that guarantees receipt, such as by mail. Preferably, use a method that documents receipt. For example, the information can be put into a parent handbook that the parent signs for.
* Use multiple contact techniques. Do everything possible to ensure parents receive notification.
* Make sure all materials are language-appropriate for parents with limited English reading ability.
* Make disapproval notification convenient. Again, use multiple venues: a written form that can be turned into a teacher, a phone number to call, or an email address. Each channel should reach a single person or office, identified in district policies, and responsible for monitoring consent. This will help prevent parent refusals from slipping through the cracks.
* Document all your efforts to notify parents.

**School District Policies**

Some school districts require active parental consent regardless of whether waiver or alteration of consent is appropriate. Researchers should check in with the participating school district(s) before the development of a passive consent process.

**NYC DOE Requirements for Research Involving Passive Parental Consent**

When conducting research in educational settings under the jurisdiction of the New York City (NYC) Department of Education (DOE), it is crucial to understand their conservative approach toward parental consent, especially when the research involves children. Here are key guidelines and considerations researchers need to follow:

Active Consent is Preferred

The NYC DOE strongly advises that research studies always aim to receive active consent from parents/guardians when working with students. This preference stems from the DOE's view of classrooms as private spaces, requiring a higher standard of privacy and consent.

Conditions for Considering Waived Consent

In unique circumstances, the NYC DOE may review requests for waived or altered parental consent on a case-by-case basis. However, researchers should be aware of the specific conditions under which such requests might be considered:

* **Teacher-Focused Studies:** If the research is focused solely on teachers and does not collect any information on students, the DOE may consider a waiver for parental/guardian consent. However, active consent must still be obtained from all participating teachers, and parents/guardians of students must be notified about the study.
* **Sensitive Subjects or Vulnerable Populations:** If the research involves sensitive topics or vulnerable groups, and observations could indirectly involve students, parents/guardians must be provided with consent forms to opt their children out of the observation, regardless of the study's primary focus.

Recording Restrictions

The use of video or audio recordings in classroom settings is strictly prohibited in studies seeking a waiver of parental consent under NYC DOE policies. This restriction is in place to protect the privacy and integrity of the educational environment.

Steps for Compliance

Researchers planning to conduct studies within NYC DOE schools should adhere to the following steps to ensure compliance with DOE policies and federal regulations:

1. Whenever possible, design your study to obtain active consent from parents/guardians. This approach aligns with the DOE's conservative stance on privacy in educational settings.
2. Even in studies where parental consent might be waived, ensure that all parents/guardians are fully informed about the study, its scope, and their rights to opt out of their children.
3. Obtain and document active consent from all teachers involved in the study, as their participation is crucial and must be fully voluntary.
4. Plan your observational methods to exclude any form of video or audio recording to comply with DOE restrictions.
5. Engage with the NYC DOE IRB early in the planning process to ensure all aspects of your study meet their requirements and to facilitate a smoother review and approval process.

**Additional Considerations and Safeguards**

* **Develop a sound plan for informing parents/guardians:** The application should explain how the consent document will be distributed to parents/guardians in a way that ensures a high likelihood that they will receive the information.
* **Provide sufficient time:** Ensure parents/guardians have enough time after receiving the consent document to read it, ask questions, and opt out before the start of research activities.
* **Make it easy to opt out:** Provide clear instructions detailing how parents/guardians may inform the researchers that they do not want their child to participate in the research.

TC IRB considers additional factors such as the size, population, data collected, study site, and complexity of the research to determine if a waiver or alteration of informed consent is appropriate. All requests will be reviewed on a case-by-case basis.

**TC IRB Related Documents**

* [TC IRB Requirements for Parent/Guardian Notification Plan for School-Based Research](#_5rulf3fbnxig)
* [TC IRB Sample Parent/Guardian Notification Form Regarding Participation in a Research Study](#_hevfv66r9q7v)

**Resources**

* General Requirements for Informed Consent, 45 CFR 46.116 (2018). URL: <https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf>.
* Health and Human Services (n.d.). *Informed Consent FAQs*. hhs.gov. URL: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>.
* Requirements for permission by parents or guardians and assent by children, 45 CFR 46.408 (2018). URL: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.408>.
* Documentation of Informed Consent, 45 CFR 46.117 (2018). URL: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117>.
* New York City Department of Education (2023). *Policy Guide*. infohub.nyced.org. URL: <https://infohub.nyced.org/docs/default-source/default-document-library/nyc-doe-irb-policy-guide_to-post_august-2023.pdf>.

# TC IRB Requirements for Parent/Guardian Notification Plan for School-Based Research

**Purpose**

These requirements ensure parents/guardians are adequately informed about school-based research involving their children, giving them a clear and timely opportunity to opt-out if desired.

**Steps for Notification**

1. **Advance Notice:**
   * Notify parents/guardians at least two (2) weeks prior to the start of the study.
   * Provide initial information via email or physical mail directly to parents/guardians to ensure it reaches them directly.
2. **Multiple Notifications:**
   * Send at least three (3) notifications using multiple methods (email, postal mail, parent-teacher meetings) to increase the likelihood of the information being received.
   * Consider using school communication platforms that parents regularly check.
3. **Content of Notification:**
   * Clearly describe the purpose of the study, what participation involves, and any potential risks or benefits.
   * Clearly state that the child will be automatically included unless the parent/guardian opts out.
   * Provide clear instructions on how to opt-out, including a direct contact email or phone number for the research team.
   * Include information on alternative activities for students who opt-out.
4. **School Collaboration:**
   * Document and include evidence of school support and agreement on the opt-out process, such as a signed letter from the school administration.
5. **Timeline and Reminders:**
   * Outline a clear timeline for parents to respond with opt-out requests.
   * Send reminder notifications a few days before the deadline for opting out.

# TC IRB Sample Parent/Guardian Notification Form Regarding Participation in a Research Study

**Principal Investigator:** Dr. Elena Mendoza  
**Faculty Advisor:** Dr. Simon Harwood  
**Study Title:** Evaluating Elementary Nutrition Education Programs in Oak Ridge Schools

**Dear Parents and Guardians,**

We are excited to share that we are conducting a research study at Maple Grove Elementary to evaluate our nutrition education programs. This study is approved by the Teachers College Institutional Review Board (TC IRB).

**Study Details:**

* **Purpose:** To measure the effectiveness of our current nutrition education curriculum.
* **Activities:** Your child will be asked to complete two questionnaires—one at the start and one at the end of the academic year. Each questionnaire will take about 10 minutes.
* **Risks:** There are no expected risks involved with participating in this study.
* **Benefits:** There are no direct benefits for participants, but the findings will contribute to enhancing nutrition education nationwide.

**Parent/Guardian Action Required:**

* **To Participate:** If you are comfortable with your child participating, you don't need to do anything.
* **To Opt-Out:** If you prefer that your child does not participate, please either:
  1. Sign and return this form to your child's homeroom teacher or Principal Greenfield’ OR
  2. Email mendoza\_research@tc.edu with "Opt-Out" as the subject line. Please include your name and your child’s name in the message.

**Deadline for Opt-Out:** September 30th.

**Contact Information:**

* **Questions:** For questions about the study, please contact Dr. Elena Mendoza at [mendoza\_research@tc.edu](mailto:mendoza_research@tc.edu) or call 321-654-9870.
* **Concerns:** For concerns about your rights as a research participant, contact our Institutional Review Board at [irb@tc.edu](mailto:irb@tc.edu).

**Notification of Refusal:**

If you do NOT allow your child to participate, please complete the following information and return it by the deadline mentioned above.

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

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Print Child’s Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian’s Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Parent/Guardian’s Name

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Date