Stanford University **HRPP**Guidance

Parental Permission for Children in School Based Studies

GUI-45

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When investigators are conducting research in school settings, obtaining permission is often done by mailing or sending home a copy of the parental permission form with the child. Investigators sometimes want to use an "opt-out process" – also referred to as "passive consent" – where the parental permission form indicates that the parent(s) should respond only if the parent(s) does <u>not</u> want their child to participate in a school activity. (E.g., schools commonly use this process for students to opt-out of sex education classes.)

For <u>research</u> purposes, an opt-out process or passive consent does <u>not</u> satisfy the regulatory requirement to obtain parental permission for participation in research. Depending on a study's purpose and risks, federal regulations state that the IRB can either:

- require signed parental permission,
- approve parental permission with a waiver of documentation (signature), or
- approve a full <u>waiver of consent</u>.

In addition to regulatory criteria for a waiver of documentation or full waiver of consent, the following should be considered:

- Is the age of the child in the study appropriate? (It may not be appropriate to waive documentation or waive consent for younger children, but may be for high school students.)
- Are the research procedures similar to those that are typically undergone in a school setting.
- Is the study subject to the <u>Family Educational Rights and Privacy Act</u> (FERPA) or the <u>Protection of Pupil Rights Amendment</u> (PPRA); if yes, then signed parental permission may be required.

If signed parental permission is required, you must get permission from the parent(s). The parental permission form can be mailed, emailed or sent home with the child. A <u>signed</u> form must be received from the parent before any research procedures can begin. If the signed permission form is not received, the child must be excluded from the study.

If a waiver of documentation is approved, there must still be a prospective <u>consent process</u> and the parent must make an active choice for their child to participate. E.g., they are emailed the parental permission form and are given a link to click "Yes" or "No" to state if their child can participate.

Resources:

GUI-C24: Children and Consenting Minors - Consent and Assent; Mandatory Reporting

GUI-C34: Parental Permission

HRPP Chapter 12.5.1

Consent forms and templates: Medical and Nonmedical