

US DEPARTMENT OF EDUCATION/ NO CHILD LEFT BEHIND GUIDANCE LEGISLATION'S IMPACT ON IRB REVIEW OF SCHOOL BASED SURVEYS AND "PASSIVE CONSENT'

Summary: The *No Child Left Behind Act of 2001* (Public Law 107-110) amended the Protection of Pupil Rights Amendment (PPRA), which concerns surveys of students, in two ways: First, it added an eighth category to the categories of protected information in surveys of minors that were already covered by PPRA. Second, it gave parents new rights with regard to the surveying of minor students, the collection, disclosure, or use of information from students for marketing purposes, and certain non-emergency medical examinations.

PPRA, as amended, has two sets of requirements for surveys : 1. Requirements that apply to "protected information" surveys that are funded in whole or in part by the U.S. Department of Education. 2. Requirements that apply to "protected information" surveys that are funded by sources other than the U.S. Department of Education and that are administered or distributed by education institutions that receive funds from any Department of Education program (i.e. public elementary and secondary schools and some private schools).

PPRA lists 8 categories of protected information for survey responses: 1. political affiliations of student or student's parent; 2. mental or psychological problems of student or student's family; 3. sex behavior or attitudes; 4. illegal, anti-social, self-incriminating or demeaning behavior; 5. critical appraisals of others with whom students have close family relationships; 6. legally recognized privileged or analogous relationships; 7. religious practices, affiliations or beliefs of student or student's parent; 8. income. (No Child Left Behind added the category 7.)

PPRA has implications for IRBs in applying the Common Rule criteria for waiving informed consent (in section 116(d) of the Common Rule). Specifically the second IRB criterion: "research does not adversely affect the rights and welfare of subjects" is impacted because of the "rights" that PPRA gives parents.

Practical Implications in Applying the Common Rule Waiver Requirement pertaining to rights and welfare:

First Set of Requirements: US Department of Education Funded Protected Information Surveys

- Does the research involve "protected information" surveys?
- Are the surveys U.S. Department of Education- funded in whole or part?
- Are the surveys "required"?

If the answer is yes to the three questions, PPRA affords parents the right to provide active consent.

Under the circumstances, it would be difficult for an IRB to determine that the "rights and welfare" criterion for waiving informed consent entirely could be met; therefore, prior written parental consent would be required, even if the IRB determined that some of the basic elements of informed consent specified in section 116(a) could be waived as inappropriate to the activity.

[Since the PPRA amendments were added fairly recently, the U.S. Department of Education has not yet written regulations providing guidance about some of the key terms in the current law. For example, the Department has not taken a position about whether the word "required" should be interpreted to mean that surveys that are clearly voluntary are exempt from PPRA requirements. Also, the law does not directly address the question of whether anonymous surveys are exempt from PPRA because anonymous surveys do not provide individually identifiable information about students or their

families Until the Department issues revised regulations implementing PPRA, IRBs need to use their judgments in complying with the first set of requirements.]

Second Set of Requirements for Protected Information Surveys that are Funded by Sources other than the U.S. Department of Education and that are administered or distributed by education institutions that receive funds from any U.S. Department of Education administered program (i.e., public schools and some private schools)

- Do the surveys include protected information?
- Are the surveys being administered or distributed by schools that receive any U.S. Department Education funds?

[Note that in this set of requirements there is no language about students being "required" to respond to the survey, so here the issue of voluntariness appears to be moot].

If the answer is yes to both questions, PPRA affords parents the right to inspect the surveys before they are administered or distributed and to opt the student out of the surveys.

PPRA requires schools to develop and adopt policies, in conjunction with parents, regarding 6 areas, some of which are relevant to surveys:

1. Right to inspect a survey before administered or distributed;
2. Arrangements to protect student privacy in the administration of a survey;
3. Right to inspect any instructional material used as part of educational curriculum;
4. Administration of physical examinations or screenings;
5. Collection, disclosure or use of personal information for purposes of marketing or selling;
6. Right to inspect any instrument in the collection of information for marketing or selling the surveys.

PPRA also requires local educational agencies to notify parents of the policies and to offer parents the opportunity to opt out of (remove child from) participation in third-party surveys involving protected information.

For IRBs, these requirements suggest that local schools have the discretion to set up their own individual policies for non- US Department of Education protected information surveys. For example, local schools can choose whether to have an active written consent policy or some other policy such as passive consent.

IRBs will have to decide how they will handle these requirements in those protocols where the investigators are requesting passive consent. For example, an IRB might require that if an investigator asks for passive consent procedures, that he/she must also document that the procedures are consistent with the policy of the local school(s) to be included in the research sample. The IRB then can use that information in determining if the "rights and welfare" criterion for waiving informed consent has been met.

US Department of Education Contact: The Family Policy Compliance Office is the office charged with administration of PPRA. Note as of March 18, 2003, the web page has the old version of PPRA. However, the Family Policy Compliance Office has released guidance documents about how No Child Left Behind revises PPRA which are on the web site.
<http://www.ed.gov/offices/OM/fpc/ppra/parents.html>

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