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.

As amended, PPRA 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 US Department of Education (DoED); and
2. Requirements that apply to “protected information” surveys that are funded by sources other than the DoED and that are administered or distributed by educational institutions that received funds from any DoED program (i.e., public elementary and secondary schools and some private schools).

PPRA now lists 8 categories of protected information for survey responses (#7 was added by “No Child Left Behind”):

1. Political affiliations of student or student’s parent;
2. Mental or psychological problems of student or student’s family;
3. Sexual 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 parents;
8. Income.

PPRA has implications for IRBs in applying the Common Rule criteria for waiving informed consent (45 CFR 115 (d)). Specifically, the second IRB criterion that “research does not adversely affect the rights and welfare of subjects” is impacted because of the rights that PPRA gives parents of subjects.

Practical Implications in Applying the Common Rule Waiver Requirement Pertaining to Rights and Welfare

First Set of Requirements: DoED Funded Protected Information Survey

- Does the research involve “protected information” surveys?
• Are the surveys US DoED-funded in whole or in part?
• Are the surveys “required”?

If the answer to the three questions is yes, 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.

Prior consent means:

Prior consent of the student, if the student is an adult or emancipated minor; or

Prior written consent of the parent or guardian, if the student is an un-emancipated minor.

Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.

Protection of Pupil Rights Amendment

For research funded by the U.S. Department of Education: No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following categories of protected information.

Income other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

(Since the PPRA amendments are relatively recent, the DoED 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 judgment in complying with the first set of requirements.)

Second Set of Requirements for Protected Information Surveys

• Do the surveys include protected information?
• Are the surveys being administered or distributed by schools that receive any DoED 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 to both questions is yes, 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 area, some of which are relevant to surveys:

1. Right to inspect a survey before administered or distributed;
2. Arrangements to protect student privacy in 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 the 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 research not funded by the US Department of Education:

The IRB must verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

- The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student.
- Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
- Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):
  - Political affiliations or beliefs of the student or the student’s parent.
  - Mental or psychological problems of the student or the student’s family.
  - Sex behavior or attitudes.
  - Illegal, anti-social, self-incriminating, or demeaning behavior.
  - Critical appraisals of other individuals with whom respondents have close family relationships.
  - Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
  - Religious practices, affiliations, or beliefs of the student or the student’s parent.
  - Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
- The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student.
- Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
- The administration of physical examinations or screenings that the school or agency
may administer to a student.

The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.

The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.

Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

Access to instructional material used in a research or experimentation program

All instructional material—including teachers' manuals, films, tapes, or other supplementary instructional material—which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.

Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

For IRBs, these requirements suggest that local schools have the discretion to set up their own individual policies for non-DoED 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 study sample. The IRB can then use that information in determining if the “rights and welfare” criterion for waiving informed consent has been met.

NOTE: The University of Alabama IRBs do not allow passive consent.

US Department of Education Contact: The Family Policy Compliance Office is the office charged with administration of PPRA. As of May 2008 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 website http://www.ed.gov/offices/OM/fpco/ppra/parents.html