

Questions and Answers from the SS/HS New Grantee Webinar:

***Human Rights and Institutional Review Boards,
Protection of Pupil Rights Amendment, and the
Family Educational Rights and Privacy Act***

January 13, 2009

1. **Question:** Please review the sharing of information with law enforcement or community agency partners regarding student behavior. If a teacher is concerned about a student's behavior, can he/she discuss that with the school resource officer (SRO) or staff of an afterschool or program run by a community agency in partnership with SS/HS? – Ivy Jones-Turner, TAS, SS/HS National T/A Center

Answer: If teachers or other personnel involved in implementing a SS/HS project have observed troubling behavior they should share concerns about student behavior with appropriate staff or officials. This type of communication supports the goals of the SS/HS Initiative to provide a range of needed prevention strategies and services to students. Grant sites may want to address issues related to information sharing in their interagency agreement or other documents that outline protocols.

Also, the Family Educational Rights and Privacy Act (FERPA) generally permits a school official to share information with outside officials that is based on that official's personal knowledge or observation. While school officials, including teachers, may discuss behavior they have observed with SROs or other appropriate professionals, as a general rule they may not disclose information if their knowledge of that information is derived from education records. Records that are directly related to a student and maintained by an educational agency or institution or by a party acting for the agency or institution are "education records" under FERPA (34 CFR § 99.3 "Education records"). Please note that this general rule does not necessarily apply where the school official who discloses information about a student based on personal knowledge or observation had an official role in making a determination that generated a protected education record. For example, under FERPA a teacher may not disclose a grade that the teacher issued to the student merely because the teacher has personal knowledge of the grade. Similarly, a principal who took official action to suspend a student may not disclose that information absent consent or some other exception permitting disclosure.

One exception to FERPA's general consent rule is the provision that permits disclosures without consent in connection with health or safety emergencies. More information about the FERPA provisions that govern disclosure of information from education records is available at: www.ed.gov/policy/gen/guid/fpco.

2. **Question:** For passive approval for surveys that cover one of the 8 covered areas, will you need to have the survey available for review by parents at the beginning of the school year? – Jerry O’Day, Project Director, Los Angeles USD

Answer: If a survey is subject to the requirements of the Protection of Pupil Rights Amendment (PPRA), parents have the right to review the content of the survey prior to administration. LEAs may provide the required notice of such surveys to parents, including the opportunity to review survey content, as part of a notification of activities covered by PPRA at the start of the school year. LEAs may also notify parents about each survey or other activity covered by PPRA throughout the year, as they are scheduled to occur. LEAs may also combine these two methods, providing information about surveys or other covered activities at the start of the school year and supplementing that notice with information about additional surveys or activities that are identified during the school year. No matter when the required notice is provided, it must provide parents with reasonable notice of the planned survey, an opportunity to review the survey, and the opportunity to opt their child out if they so desire.

In addition, if the study is covered by the Common Rule for the Protection of Human Subjects in Research (34 CFR 97) passive approval (aka “opt out”) consent procedures would have to be approved by the IRB.

3. **Question:** Do each of our contractors need an FWA? – Jerry O’Day, Project Director, Los Angeles USD

Answer: If the study is covered by the Common Rule for the Protection of Human Subjects in Research (34 CFR 97) as including nonexempt human subjects research, the grantee must have a Federal Wide Assurance (FWA). In addition, contractors or any other entities that will be engaged in research must also have a FWA on file with the Office of Human Research Protections and IRB approval before data is collected or the project is evaluated. Guidance on what constitutes engagement in research is available at the Department of Education (ED) protection of human subjects web site: <http://www.ed.gov/about/offices/list/ocfo/humansub.html>.

4. **Question:** Are the GPRA measures considered part of the 8 protected areas? – Stacy Rychener, Evaluator, Putnam County ESC

Answer: GPRA, or the Government Performance and Results Act, is a statute that requires all Federal agencies to develop annual reports and plans for the programs that they manage that emphasize accountability and program results. We have established the following GPRA performance measures related to student victimization/perception of school safety, student substance use and abuse, and mental health service provision for the SS/HS grant program:

1. Percentage of grantees that experience a decrease in students who did not go to school on 1 or more days during the past 30 days because they felt unsafe at school or on their way to and from school.
2. Percentage of grantees that experience a decrease in students who have been in a physical fight on school property in the 12 months prior to the survey.
3. Percentage of grantees that report a decrease in students who report current (30-day) marijuana use.
4. Percentage of grantees that report a decrease in students who report current (30-day) alcohol use.
5. Percentage of grantees that report an increase in the number of students receiving school-based mental health services.
6. Percentage of grantees that report an increase in the percentage of mental health referrals for students which result in mental health services being provided in the community.

Generally, survey questions concerning alcohol or drug use or fighting (like those associated with GPRA measures 2, 3 and 4) would be associated with illegal, anti-social, self-incriminating, or demeaning behavior, the fourth of the protected areas established by PPRA. The eight protected areas are:

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. Sexual behavior or attitudes;
4. Illegal, anti-social, self-incriminating, or demeaning behavior;
5. Providing a critical appraisal of someone with whom the respondent has a close family relationship to;
6. Legally recognized privileged or analogous relationships (i.e. doctor, lawyer, clinician, or clergy member);
7. Religious practices, affiliations, or beliefs; and
8. Income.

If a student survey given at school asks questions about any of the eight protected areas identified by PPRA, parents have the right to consent. (In addition, if the study is covered by the Common Rule for the Protection of Human Subjects in Research, 34 CFR 97, the IRB may also require parental consent.)

5. **Question:** We are only collecting data for evaluation performance purposes and we will not be presenting at any venue. Do we need IRB approval? – Stacy Rychener, Evaluator, Putnam County ESC

Answer: Based on the limited information provided in the question, it does not appear that your evaluation activities constitute research. In this case, you would not need to provide an FWA or secure IRB review and approval. However, the information provided may not include all of the details needed to make a final determination. We would suggest you contact your FPO and possibly submit your plan to Jeff Rodamar, the Protection of Human Subjects Coordinator at the U.S. Department of Education (telephone: 202-260-3353;

fax: 202-205-0765; and e-mail: jeffery.rodamar@ed.gov
<http://www.ed.gov/about/offices/list/ocfo/humansub.html>).

6. **Question:** We are collecting no personally identifiable data on students or family as part of the evaluation. Does this apply to us? – Steve Snider, Evaluator, Page USD

Answer: If the participant is asking if PPRA applies to them if the survey is not personally identifiable to students, then the answer is “yes”—anonymity is not relevant. If “we” is a grantee outside the school, FERPA would prohibit the school from disclosing to the grantee information on students in personally identifiable form. The school would have to either get consent from parents or de-identify the data. New FERPA regulations explain and expand on this.

Further, if a study includes no interaction with directly or indirectly identifiable data about individual study participants, then it is not covered by 34 CFR 97. Note that 34 CFR 97 applies not only to students and their families but to other study participants including but not limited to teachers, principals, and school counselors. Data sets in education research often include many indirect identifiers, even after direct identifiers are coded or removed.

7. **Question:** With regard to the Common Rule, if it’s NOT research, then no IRB is needed. Is this regardless of whether or not human subjects are involved? So, in your list under the Common Rule, should it read: “If it is research, are human subjects involved?” – Miriam Resendez, Evaluator, Campbell County School District

Answer: If it is not research, then no FWA or IRB approval is needed. Some research may not involve human subjects—for example, if only aggregate data (i.e. school level data) is used or if the data is not directly or indirectly identifiable. The Common Rule applies if it is research and if it includes human subjects (interaction with and/or directly or indirectly identifiable information about individuals in the study).

8. **Question:** I'm still confused about this. I just planned to get approval from OU's IRB for this project. Are you saying I need to do more than that? – Margaret Hutzel, Evaluator, Bellaire School District

Answer: If the Common Rule applies to your SS/HS grant, it has three requirements:

1. That there is a Federal Wide Assurance for the grantee and any other entities that will be engaged in the research;
2. That there is initial and continuing Institutional Review Board review and oversight that covers each entity engaged in the research; and

3. That there is informed consent or parental permission and assent unless modified or waived by the IRB. (Note that FERPA and PPRA do not permit waiver of consent.)

If a SS/HS project is subject to the Common Rule, the grantee (LEA) may have its research activities reviewed by an IRB maintained by the LEA, a university, or another organization that supports an IRB. However, the grantee (LEA) must have filed the required FWA. The fact that the review is being conducted by an IRB maintained by a university does not alleviate the need for the grantee to provide an FWA, even if the university sponsoring the IRB that was used has an FWA on file. If you have a question about whether the Common Rule applies to your grant program, please contact your federal project officer (FPO) and/or Jeff Rodamar.

9. **Question:** Just to clarify, an evaluator at a university can work with their IRB and then submit that approval to ED. Correct? – Margaret Hutzler, Evaluator, Bellaire School District

Answer: If a SS/HS project is conducting research and requires IRB review, that review can be provided by an IRB maintained by a university. The grantee (LEA) would need to list that IRB(s) on its FWA and submit to ED proof of initial IRB approval, as well as required annual review/certification.

10. **Question:** At the last 2 PRIM&R (for IRB professionals) conferences, it was emphasized that the Dept of Ed does not recognize passive consent. Did today's presentation imply that passive consent is now acceptable? – Leslie Page, Evaluator, Eudora School District

Answer: The description of the ED position in your question is not accurate (as noted by Jeff Rodamar who presented at PRIM&R). The Common Rule permits an IRB to waive or modify informed consent in minimal risk studies. However, depending on the study design, other statutes such as PPRA, FERPA and/or HIPAA may apply. Those statutes may require consent even if it were to be waived by the IRB.

In the webinar, we stated that when there are surveys funded by the Department of Education that students are required to take—under PPRA schools must obtain written consent from parents (“active consent”) prior to giving the survey. If the survey is not funded by the Department but the school generally receives funds from any program administered by the Department, then you must apply the direct notification and opt-out requirements in PPRA, frequently considered “passive consent.” What constitutes “required” has raised questions in many districts; therefore, if you have any questions about which type of consent to use, you should email PPRA@ED.Gov for guidance.

11. **Question:** What specific language is needed to inform students/parents that participation in a survey is not required? – Frank Mondeaux, Evaluator, Ronan School District-Klamath Falls School District

Answer: Again, the issue is more complicated than just saying that participation is not required—surveys can be administered in a way that suggests that participation is expected. You should review the information on the Family Policy Compliance Office’s (FPCO) website that provides model language for notifying parents. See the September 2008 notices to SEAs and LEAs at this link:

<http://www.ed.gov/policy/gen/guid/fpco/hottopics/index.html>.

12. **Question:** Is an entity defined as an LEA or a local school building? – Laura Krebbs, Research Assistant, NET

Answer: The entity is defined as the LEA.

13. **Question:** Last year we qualified as exempt for IRB because we did not publish the report and were not a university. Is this still the case? – Jodi Koren, Evaluator, Taylor County and Middle GA SS/HS Initiative

Answer: Intent to publish is a helpful proxy indicator of whether a study is research. However, publication is neither necessary nor sufficient to make a study research. For example, many things are published that are not research under the Common Rule—and important research is never published. Similarly, whether an institution engaged in research is a university has no bearing on whether a study is covered by the Common Rule.

ED makes the final determination of whether a proposed study is covered by the Common Rule. Grantees, in consultation with ED, will need to determine if they are conducting research, as defined by the Common Rule, to determine if research activities associated with their project require IRB review.

14. **Question:** If an evaluator has an IRB (with a Federal wide Assurance), does the LEA have to apply for their own? – Amy Vincus, Evaluator, Pender County, Randolph County, and Rowan-Salisbury

Answer: If covered research is conducted under an ED grant, the grantee must have a FWA. Each entity that is conducting the research (“engaged in research”) must have IRB approval. If the grantee is not engaged in research (since the evaluator is conducting all the research activities) then only the evaluator would need IRB approval and its own FWA. If both the LEA and evaluator are engaged in research (i.e. teachers handing out and collecting surveys

as part of the research) then both would need IRB approval but the evaluator's IRB could provide approval for both entities.

15. **Question:** What type of publication classifies it as research? If we put evaluation findings on our SS/HS website, does this mean we need the IRB review? – Dan Burke, Project Director, Santa Fe Public Schools

Answer: Again, intent to publish (which may include publication on websites) is a helpful proxy indicator of whether a study is research. However, publication is neither necessary nor sufficient to make a study research. As was stated earlier, many things are published that are not research under the Common Rule and some important research is never published.