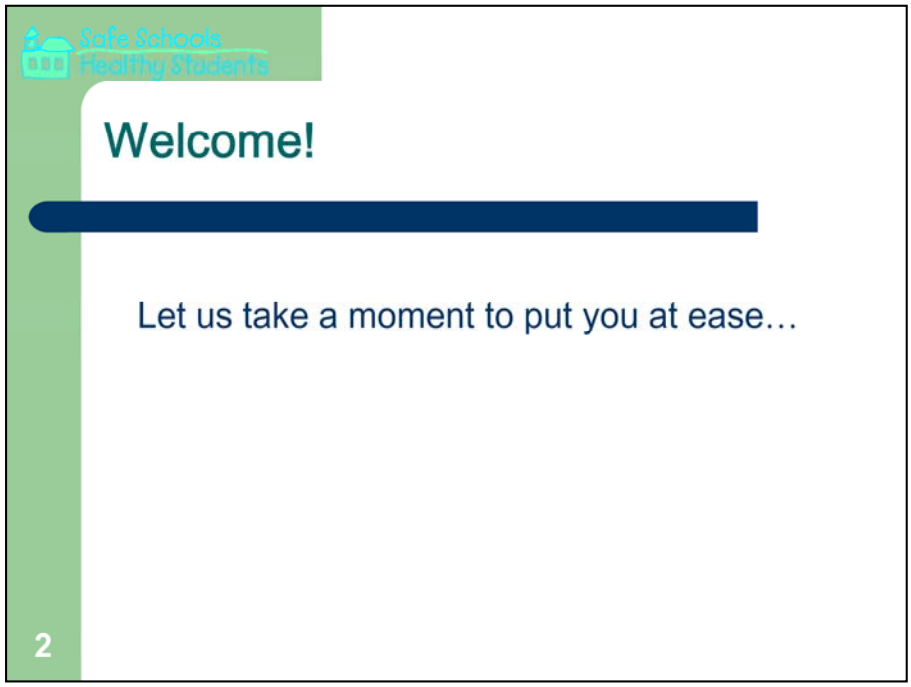
Hello and welcome to the Safe Schools/Healthy Students webinar addressing The Common Rule for the Protection of Human Subjects, the Protection of Pupil Rights Amendment, and the Family Educational Rights and Privacy Act.

My name is Wendie Veloz and I am a SS/HS federal project officer from the U.S. Department of Health and Human Services. Also presenting today is Eve Birge, my fellow SS/HS Federal Project Officer with the U.S. Department of Education.



This afternoon we will cover a lot of information. The purpose of this webinar is to familiarize you with three areas that relate to protecting the rights of people involved in your grant program. You are not expected to remember everything we cover today and we do not expect you to make determinations based on this presentation. We will provide additional resources and contact information for people who can help you with specific issues and provide additional expertise.

Twice during this webinar we will pause to take any questions you might have. Ben has already told you how to submit questions using the webinar technology. Please note that we will not be able to provide answers to questions that are unique and specific to your grant application or grant site. If you have site specific questions we will ask that you contact your Federal Project Officer for assistance. Due to the complexity and technical nature of these topics, there may be some questions we will not be able to answer. If this happens, we will research the question and post the answer on-line or we will follow up with you individually. We will provide you with the web address where you can access this presentation and corresponding notes at the end of this discussion.

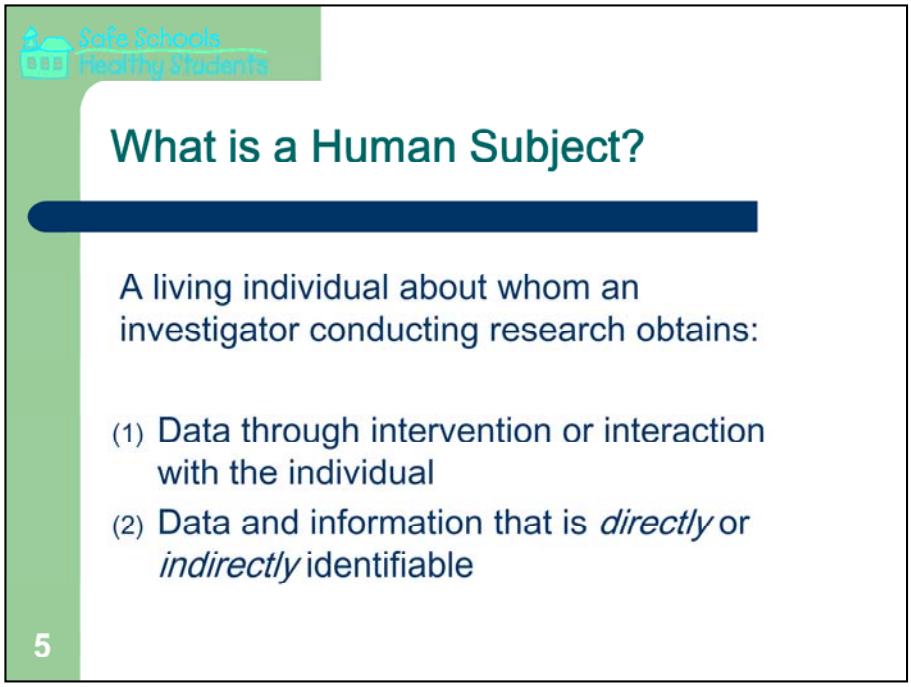
The first topic to be addressed is the protection of human subjects in research and the role of Institutional Review Boards (IRB) in protecting human subjects. Compliance with the regulations addressing the protection of human subjects is dependent on your evaluation's proposed data collection procedures and the population to be served. During this portion of the webinar I will help define the terms on this slide and also provide information which will help you to determine if the Common Rule might apply to your SS/HS program. If you think the Common Rule might apply, this webinar will also help you determine if your SS/HS grant application and evaluation plan will need to be reviewed by an Institutional Review Board.

As background, there are three ethical principles that cover human subjects involved in research:

The first principle is “Respect for Persons” which means that through informed consent you provide people with choice and knowledge of risks.

The second principle is Beneficence. That is, the potential benefits outweigh the risks -- in other words, do no harm.

And the third principle is Justice. That there is equitable distribution of burdens and potential benefits. In other words, the risks and benefits are not biased towards one group or another.

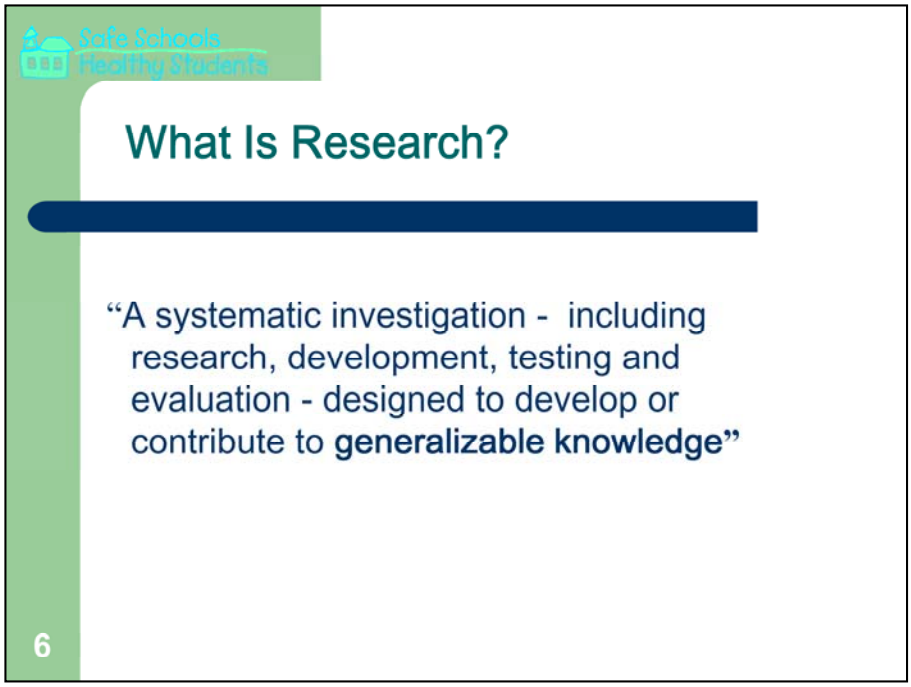


Let's start with the definition of a human subject. A human subject is a living individual about whom an investigator conducting research obtains two things:

1. data through intervention or interaction with the individual; and
2. identifiable private data or information.

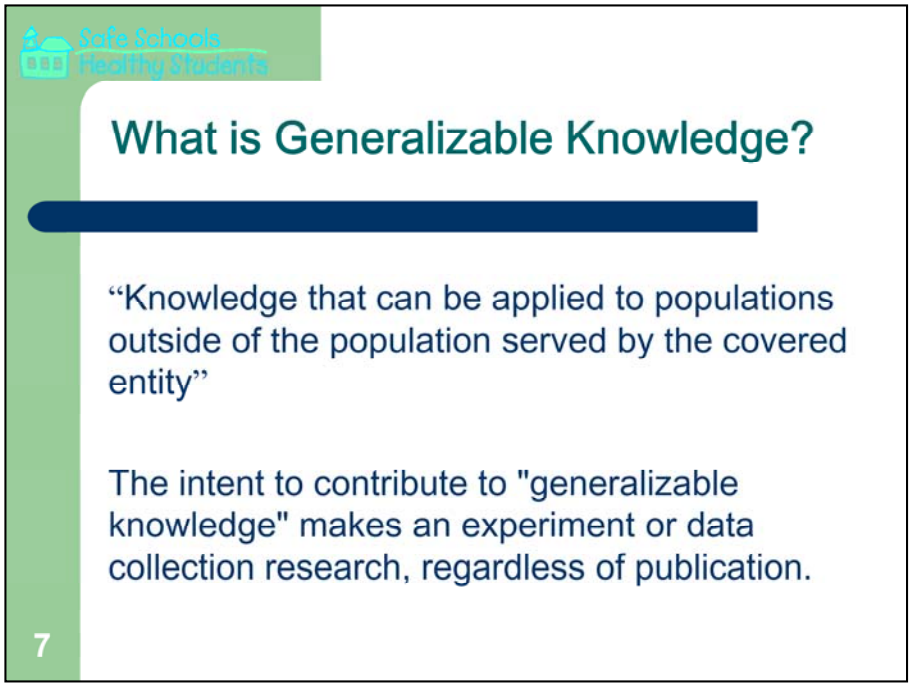
Please note that there can be directly identifiable data and indirectly identifiable data. Examples of directly identifiable data would be such things as a person's name, their social security number or their address. Examples of indirectly identifiable data are a person's date of birth, their sex, and even their five digit zip code.

A recent study by the Journal of the American Medical Association indicated that even if you strip out all the directly identifiable data in a data set, that you can still identify 87% of the individuals if you only know their birth date, their sex, and their zip code.



Let's talk for a moment about what constitutes research. Research is defined as a systematic investigation – that includes research, development, testing, and evaluation – and is designed to contribute to generalizable knowledge. It is not considered research if:

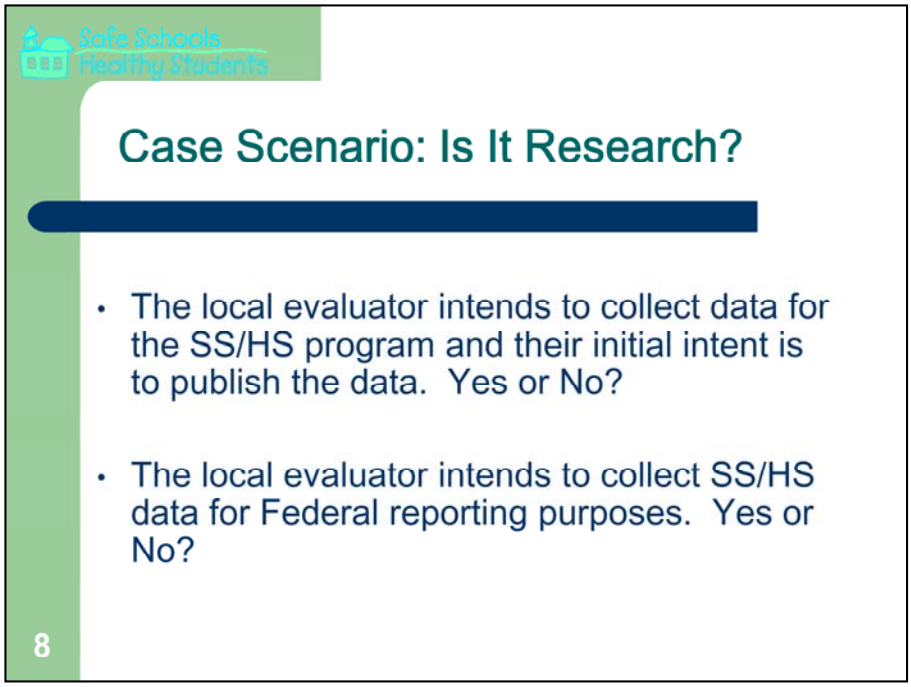
- There is a lack of systematic methods of data collection and analysis
- There are no human subjects
- Findings apply only to a local site, the study is unique, and does not generalize, and
- You are only monitoring implementation of a proven treatment in the same or a similar population



On the previous slide I used the term "generalizable knowledge" as part of the definition of research. Very simply, generalizable knowledge is knowledge that can be applied to populations OUTSIDE of the population being served.

Investigations designed to develop or contribute to generalizable knowledge are those that draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (for example: publications or presentations). Note that the results of an evaluation do not have to be published or presented to qualify it as research. The key point to keep in mind is that it is the INTENT to contribute to "generalizable knowledge" that makes an experiment or data collection research, regardless of whether it is published or presented. Research that is never published is still research and participants in research studies deserve protection whether or not the research is published.

If there is any possibility that any part of the evaluation of your SS/HS program would contribute to generalizable knowledge, you should get IRB approval before you begin to collect any data. We want to emphasize that no covered research can be conducted until the study has been cleared by the Dept. of Education Human Subjects office. There could be a major impact on an evaluation and on grantee performance if there are delays in getting IRB approval for a covered study. Please think about this BEFORE you begin your grant activities and/or collect data.



Let's take a moment to look at some scenarios to test your understanding of what constitutes research and generalizable knowledge. These two scenarios will test your knowledge of research:

1. In the first example…

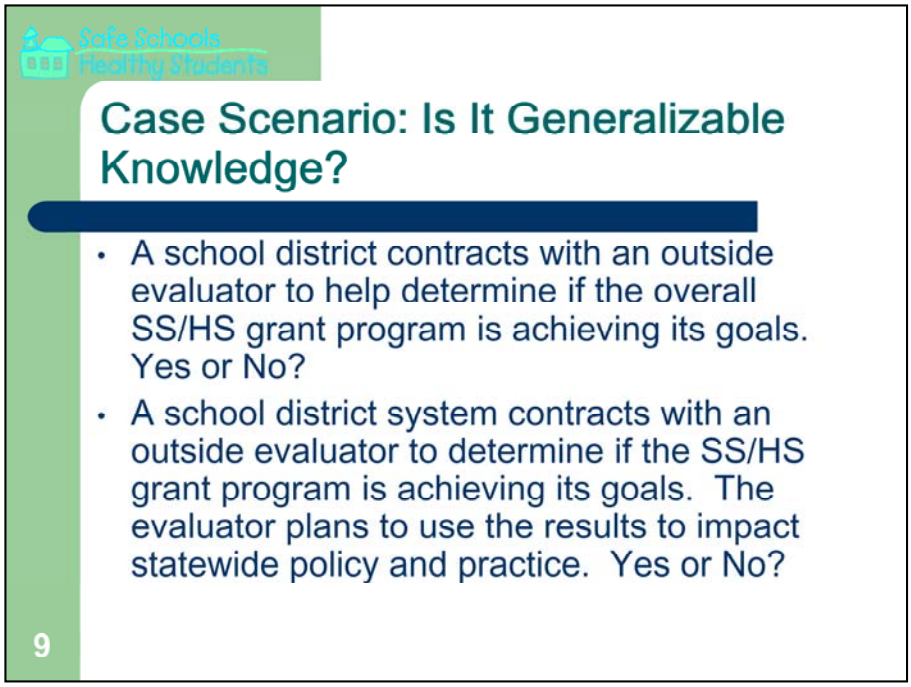
The local evaluator for a SS/HS grant program intends to collect data for the program and the evaluator's initial intent is to publish the data at a later date. Is this consideredresearch?

The answer is yes since the data is being collected as part of a systematic investigation and the evaluators intent is to use the data in a publication, thereby making a contribution to generalizable knowledge.

2. In this second scenario, the local SS/HS evaluator intends to collect data for Federal reporting purposes. Is this considered research?

It might not be. Simply collecting data does not necessarily imply that it is research and reporting that data for Federal reporting purposes does not contribute to generalizable knowledge. But, if in addition to Federal reporting, the evaluator intends to present the data and findings at an upcoming conference, then it would be considered research.

As you can see, rarely are there clear-cut answers. For this reason, you should work with your evaluator, your Federal Project Officer, and the Department of Education to determine if you are conducting research and are therefore required to seek IRB approval.



Now let's take a quick quiz about generalizable knowledge:

1. A school district contracts with an outside evaluator to help determine if the overall SS/HS grant program is achieving its goals. Is this considered generalizable knowledge?

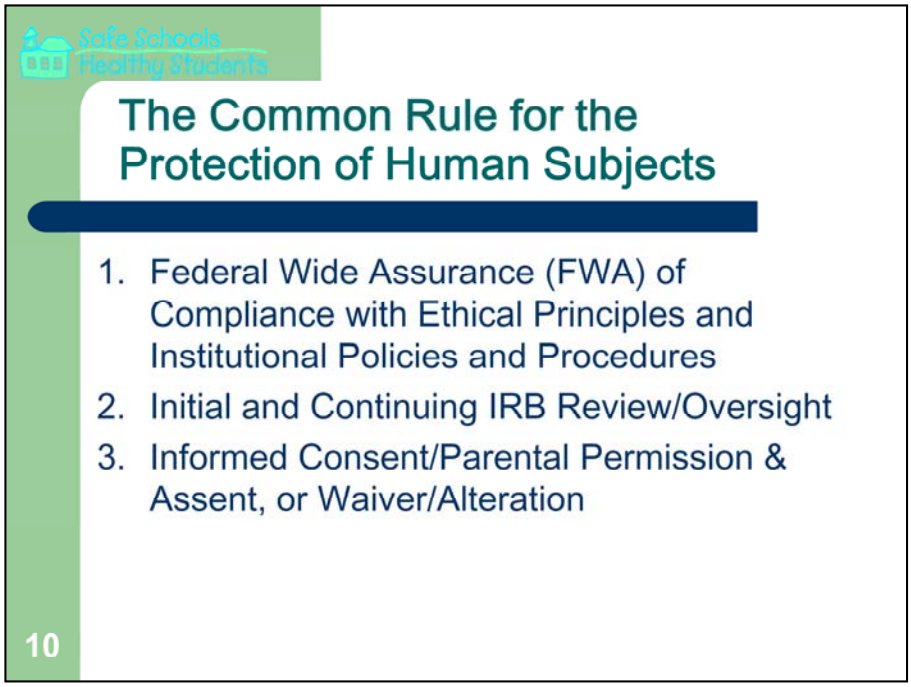
The answer is NO. In this example, the evaluation is focused on the work and progress of a specific school system and will not be generalized or shared publicly. <u>If the evaluation does not contribute to generalizable knowledge, then it is not research.</u>

2. A school system contracts with an outside evaluator to help determine if the overall SS/HS grant program is achieving its goals. Additionally, the evaluator plans to use the evaluation results to impact statewide policy and practice. Is this generalizable knowledge?

In this case, the answer is yes. That is, this would be considered generalizable knowledge since the evaluator plans to communicate the evaluation findings publicly, in this case for the purpose of impacting policy and practice.

It is best to go the conservative route, meaning that if you think you will use the data and information from your evaluation to contribute to generalizable knowledge, you should go through the IRB process now rather than later.

You cannot retroactively obtain IRB approval.



The Common Rule is a Federal policy regarding human subjects protection that applies to 17 Federal Departments and agencies, including both the Departments of Education and HHS. The main elements of the Common Rule include: assuring compliance by research institutions, researchers' obtaining and documenting informed consent, and, Institutional Review Board membership, function, operations, review of research, and record keeping.

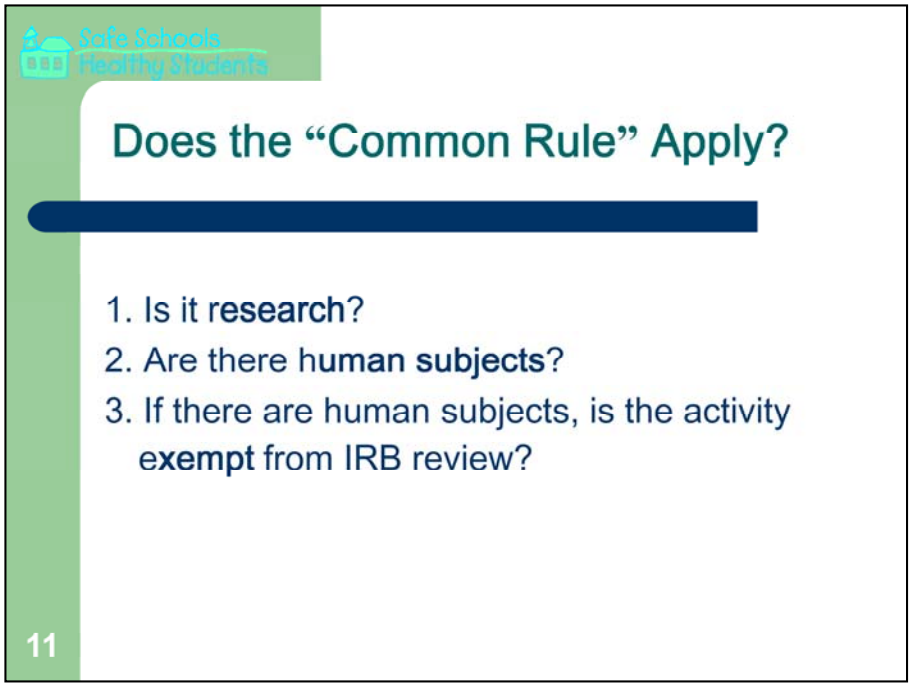
"The Common Rule" has three requirements:

1. That there is an assurance of compliance with ethical principles and institutional policies and procedures – this assurance is known as a Federal Wide Assurance;

2. That there are both initial and continuing (at least annually) IRB reviews and oversight; and lastly,

3. That there is informed consent or parental permission & assent – this is usually needed unless it's waived by an Institutional Review Board.

We will review these three requirements and describe how the Common Rule might apply to you as a SS/HS grantee.

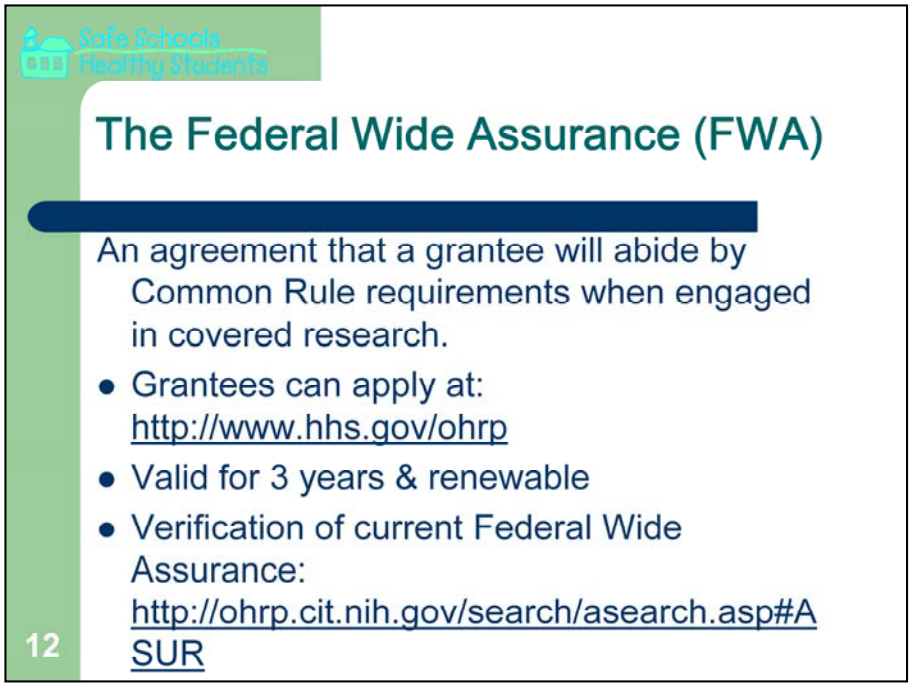


So the question becomes -- does the common rule apply to your SS/HS grant and therefore do you need to move forward with IRB review?

There are three questions you need to ask to determine if the Common Rule applies to your SS/HS grant program:

1. Is it research? If it is not research, IRB review is not needed.
2. Are there human subjects? If there are no human subjects, IRB review is not needed.
3. If there are human subjects, is the activity exempt from IRB review? If the activity is exempt, IRB review is not needed.

In relation to point #3 – is the activity exempt from IRB review? – you should note that as the funding agency, the Dept of Education Human Subjects Office makes the final determination of whether a study or activity is exempt from IRB review.



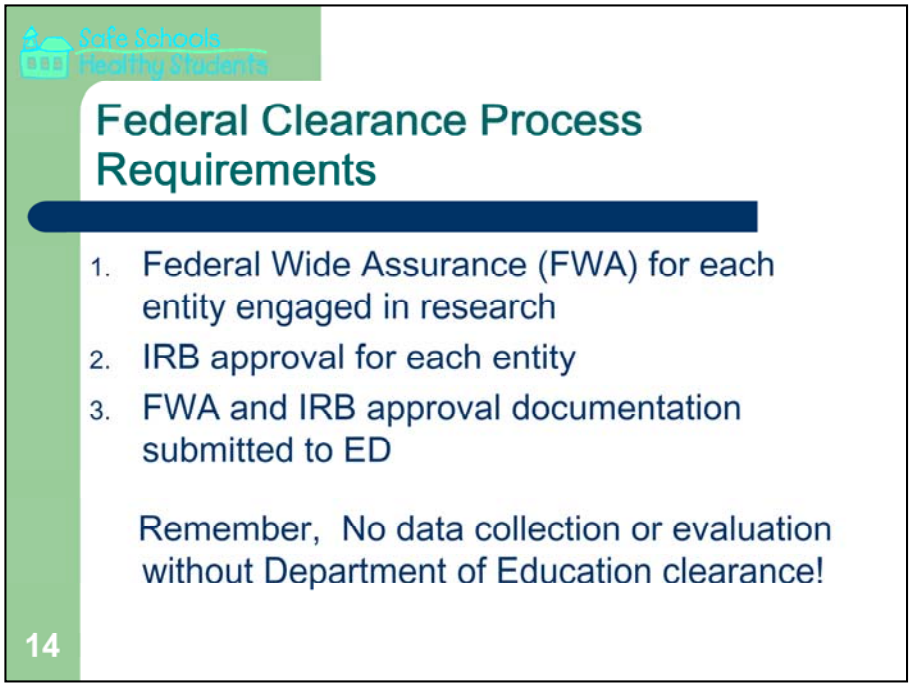
If the common rule applies, the first requirement is that there be a Federal Wide Assurance. This is a generic agreement that the grantee will abide by Common Rule requirements when engaged in covered research. Any Local Education Agency (LEA) that is engaged in research funded by one or more of the Common Rule agencies (including the departments ED and HHS) must have a Federal Wide Assurance. The Dept. of HHS Office of Human Research Protections is the agency that issues the Federal Wide Assurance and grantees can apply for the Federal Wide Assurance at the website on this slide. The Federal Wide Assurance is valid for three years and is renewable. If your project is subject to the Common Rule, as a condition of an SS/HS grant award you are required to provide documentation that the Federal Wide Assurance is on file with the Office of Human Research Protections and that IRB approval has been received before you collect data or evaluate the project.

Most school districts do not already have a Federal Wide Assurance in place. But, if you want to check to see if you do, you can go to the second website noted on this slide to check as well as to verify that the Federal Wide Assurance has not expired.

Throughout the presentation we have made reference to institutional review boards, also known by the acronym IRB. An IRB is a group of five or more people who have been formally designated to approve, monitor, and review research involving human subjects with the aim to protect their rights and welfare. Many universities and evaluation firms have their own IRB. If an institution does not have an IRB they have three options. First, they can form their own IRB. As an example, several years ago the NYC school system had a research review committee that decided to register as an IRB so that teachers and others conducting studies in the school system did not have to go through multiple reviews of the same study. The second option is to ”borrow” an IRB from a local college or evaluation firm. The third option is to contract with one of the various commercial IRBs.

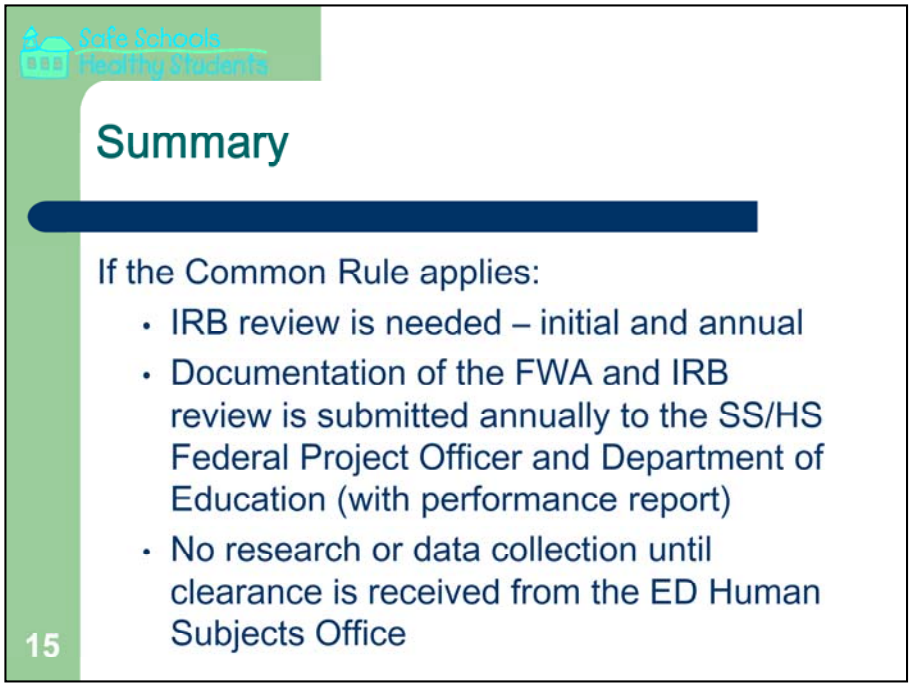
You should note that all IRBs must be registered with the Office of Human Research Protections within the US Dept of Health and Human Services. Many school districts have committees that review proposed studies but these committees may not be registered with the Office of Human Research Protections. If they are not registered, they cannot provide IRB approval.

If an IRB is not already in place in your district, SS/HS grant funds can be used to cover IRB costs.



If the common rule applies to you, the Dept of Education will need to clear your SS/HS study. To accomplish this, you are required to provide the Department of Education with a Federal Wide Assurance and documentation of IRB approval for each entity engaged in the research before you begin to collect data.

As a condition of being awarded Federal funds, you are required to provide the documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP) and that IRB approval has been received, again, prior to collecting data or evaluating the project.

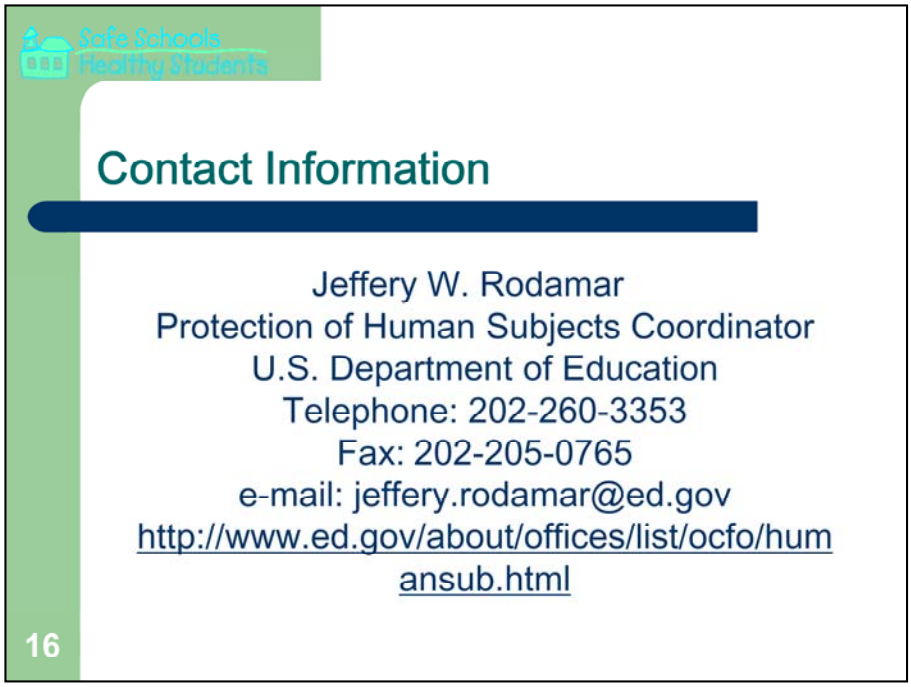


To summarize:

•IRB continuation approval is required at least once a year and documentation of approval should be submitted with the annual performance report or to your FPO if the annual date is different from the performance report date

• Grantees need a Federal Wide Assurance and IRB review if they are engaged in research

•No research should be undertaken until it has been cleared by Department of Education's Human Subjects Office



Jeff Rodamar is the Protection of Human Subjects Coordinator at the Department of Education. If you have questions about human subjects and institutional review boards, he's the man to talk to!

Now we will break for questions.

Please remember if you have a site specific question, we invite you to contact your FPO and they will work with you and Jeff directly.

Break for questions and switch presenters

Safe Schools Healthy Students

Questions?

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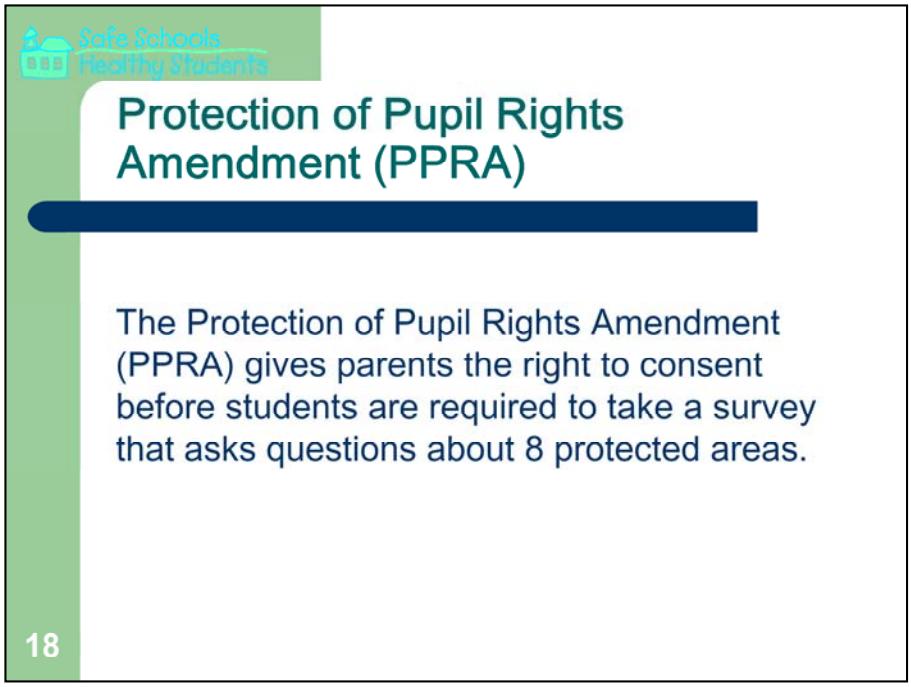
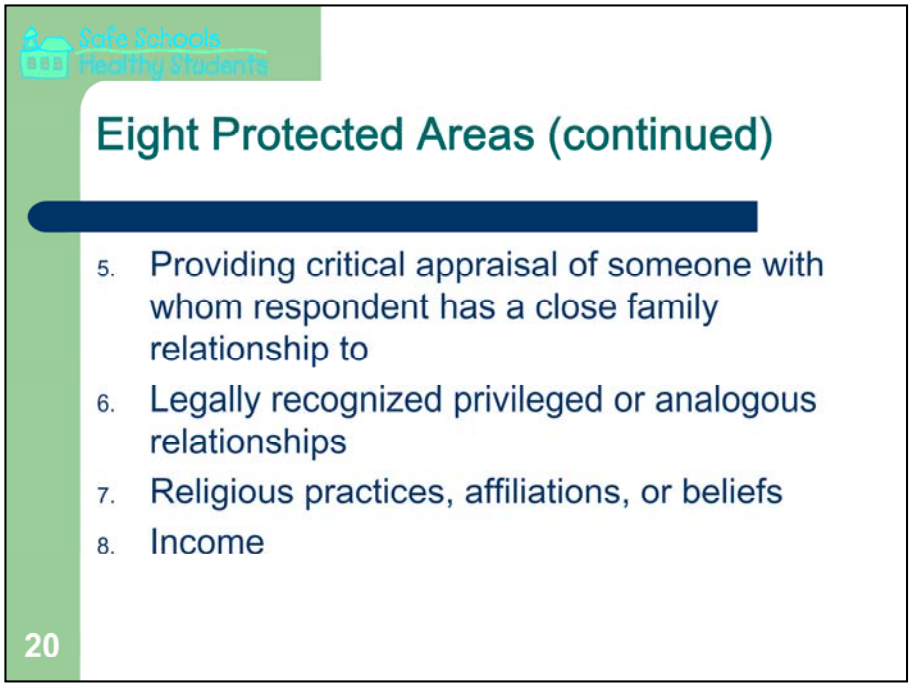


Good afternoon. My name is Eve Birge and I work in the Office of Safe and Drug-Free Schools as a SS/HS federal project officer. Thanks to everyone who tuned in to this webinar. As Wendie highlighted at the beginning of the presentation, we don't expect you to remember everything we share today, but it's important that you have this language and the over-arching concepts about student and family protections on your radars – for their protection and ultimately for your protection.

I'm going to take a few minutes to review the Protection of Pupil Rights Amendment. PPRA gives parents and guardians, hereafter referred to as parents, the right to consent before students are required to take a survey that asks questions about 8 protected areas.

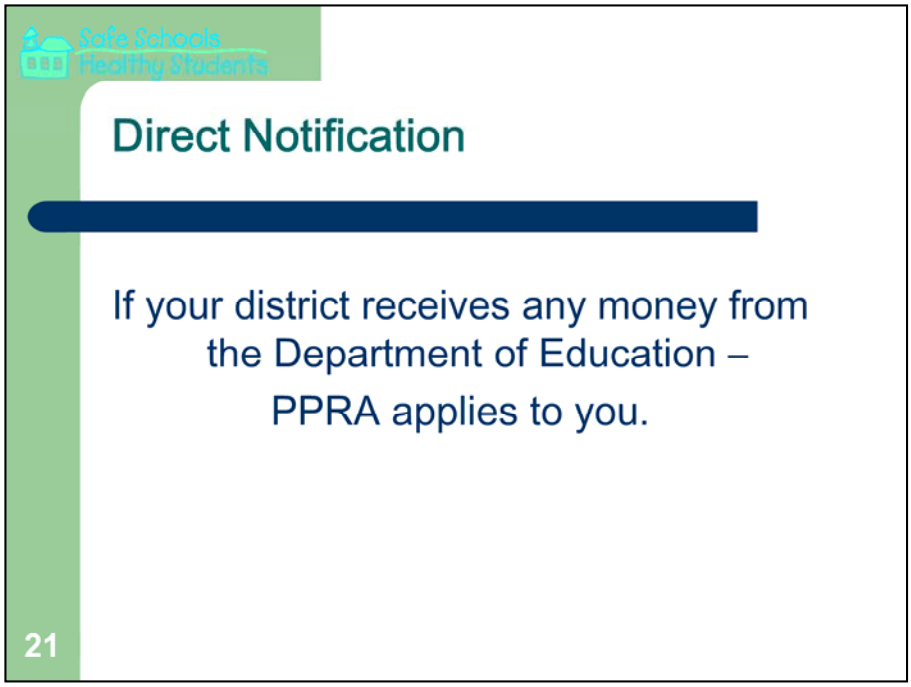
The 8 protected areas are:

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;



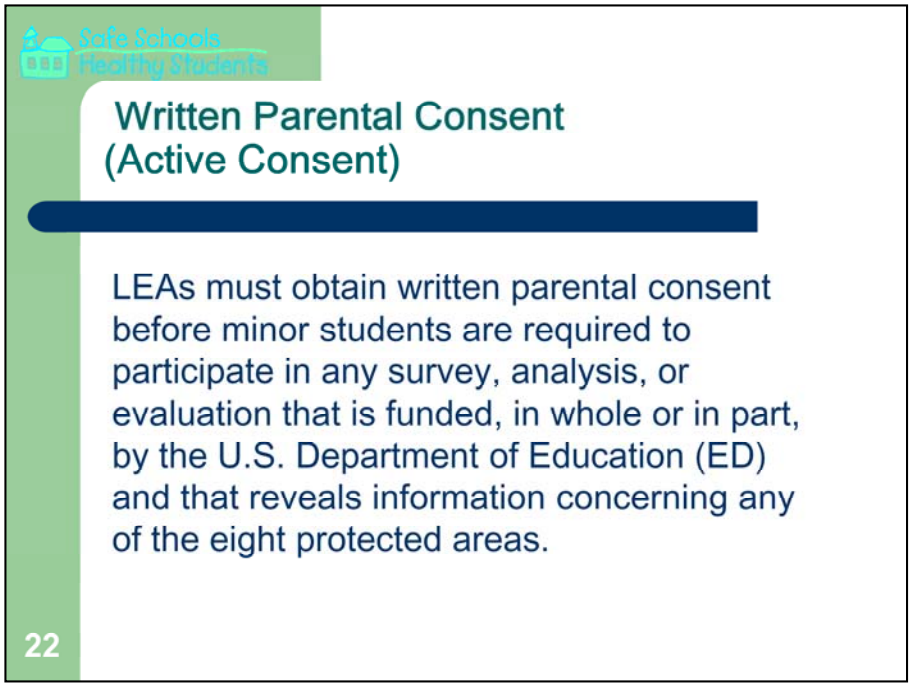
5. Providing a critical appraisal of someone with whom the respondent has a close family relationship to;
6. Legally recognized privileged or analogous relationships (i.e. doctor, lawyer, clinician, or member of clergy);
7. Religious practices, affiliations, or beliefs;
8. And income.

Again, if a survey asks questions about any of these areas, parents have the right (under PPRA) to consent before a student is required to take it.



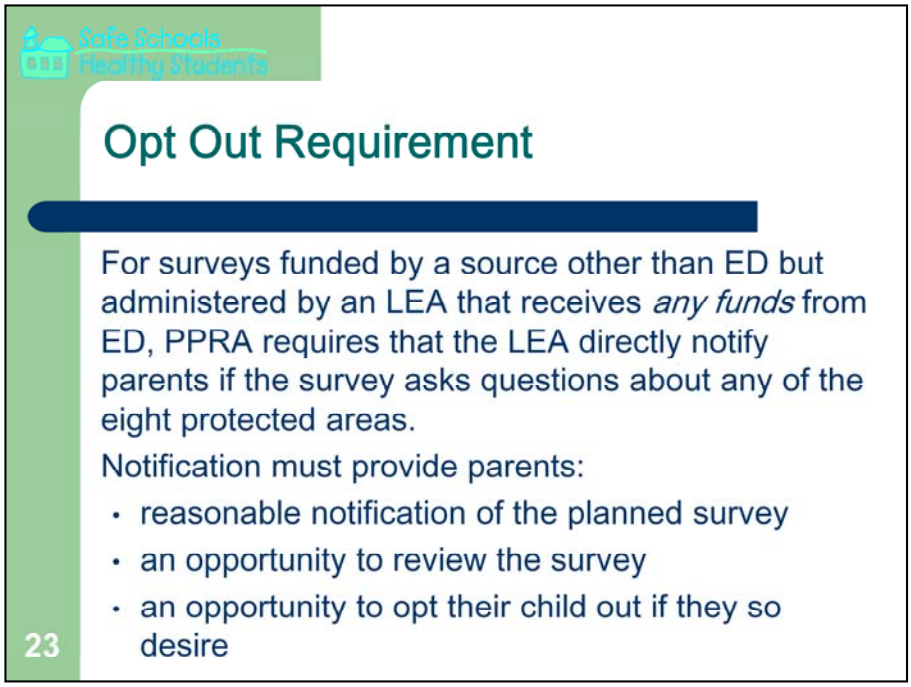
If your local educational agency receives any funds from the Department of Education, whether the survey is directly funded by the Department of Education or not, PPRA requires that the LEA directly notify, through U.S. Mail or email, parents of students who are scheduled to participate in a survey that asks questions about any of the eight protected areas.

This means that if your district receives any money what so ever from the Department of Education, PPRA applies to you. As SS/HS grantees, this means YOU.

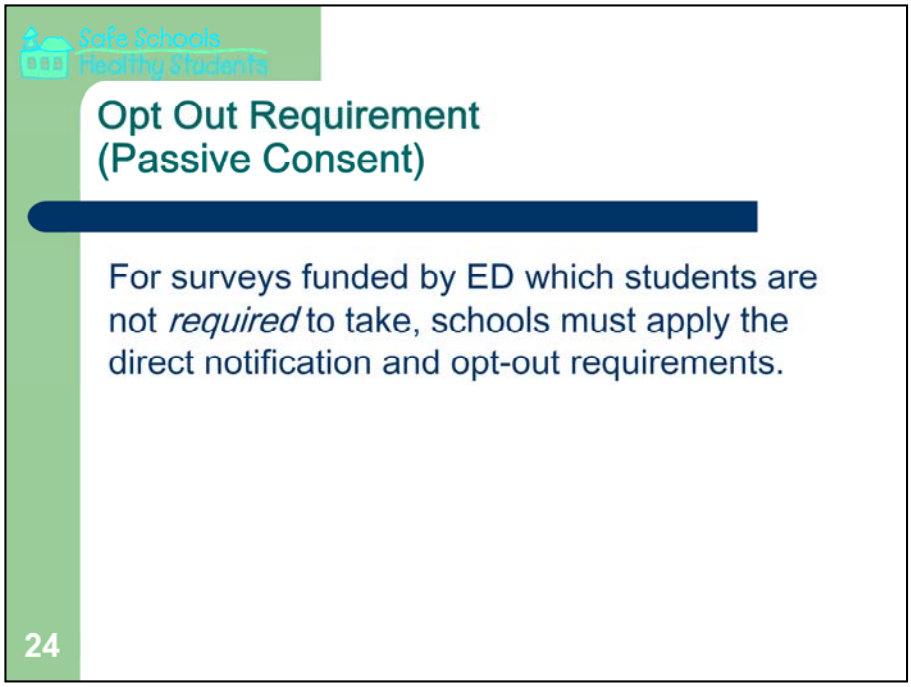


Under PPRA, schools must obtain written parental consent before minors are required to participate in any survey, analysis, or evaluation that is funded, in whole or in part, by the U.S. Department of Education and if the survey collects information about any of the 8 protected areas I just mentioned. This is considered “active consent.”

Active parental consent means that a parent has to sign a consent form before his/her child can be included in a study. A lack of response is treated as a refusal to participate *in the research*.

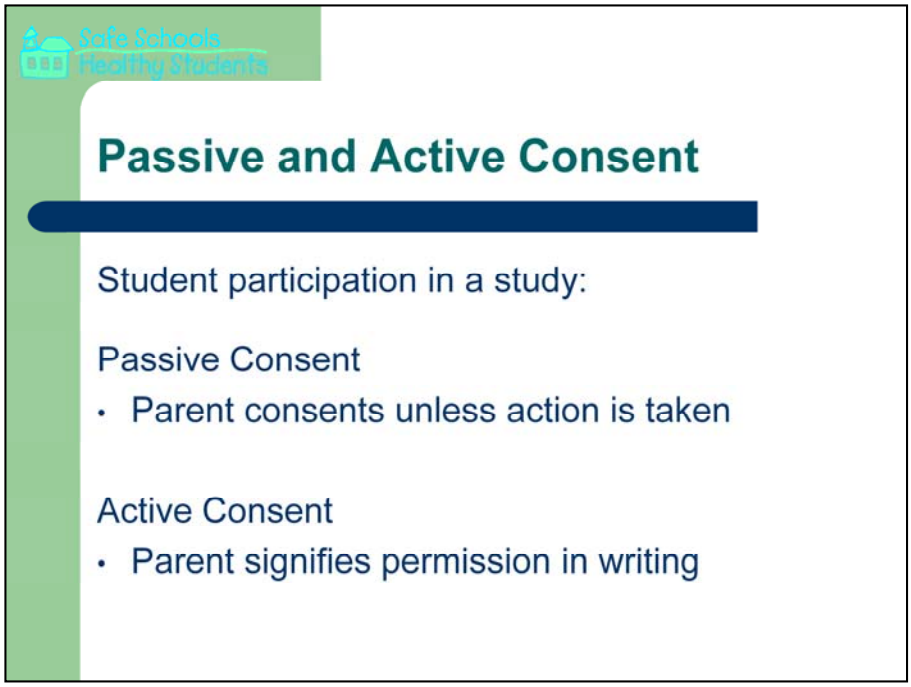


For surveys funded by a source other than Department of Education but administered by an LEA that receives funds from any program of the Department of Education, PPRA requires that the LEA “directly” notify, such as through, parents of students who are scheduled to participate in a survey that asks questions from one or more of the eight protected areas that I listed earlier. This notification must provide parents with reasonable notice of the planned survey, also it must provide parents with an opportunity to review the survey, and provide them with an opportunity to opt their child out if they so desire.

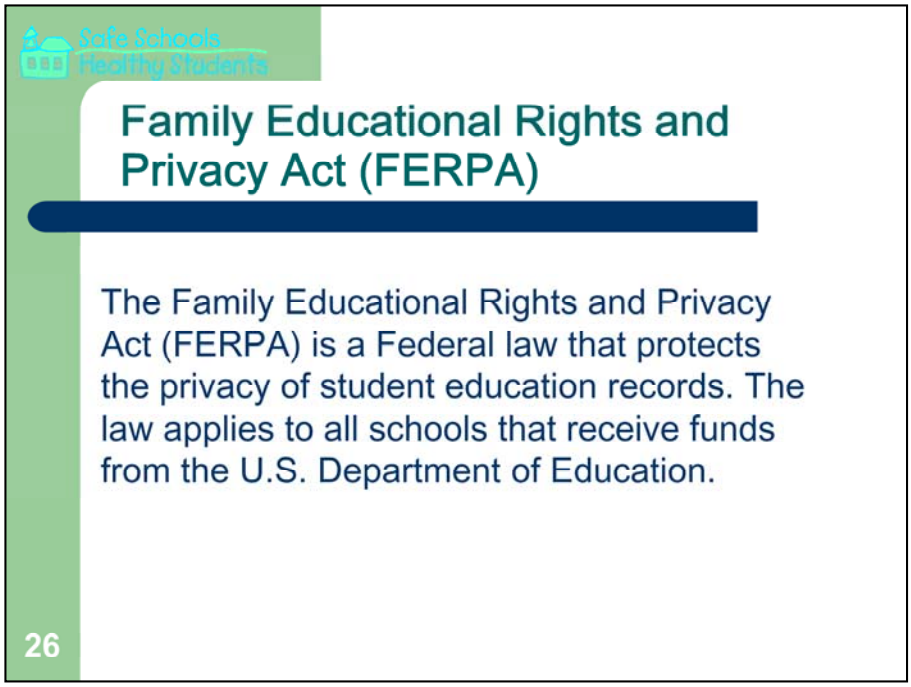


For surveys funded by the Department of Education that students are not required to take, schools must apply the direct notification and opt-out requirement. This is considered “passive consent.”

Using passive parental consent procedures, rather than active (written) consent, parents inform the school only if they do not want their child to participate in a study (or the opt the child out).



As you can see, active and passive consent methods differ in important ways. A passive consent procedure typically involves distributing a letter to the children's parents explaining the nature of the study and providing a method to retract or withdraw permission. In an active consent procedure, the letter explains the nature of the study and provides a method to document permission. The important distinction between these two procedures is that passive consent assumes that the parent has consented unless some action is taken, whereas active consent requires the parent to signify in writing their permission for the minor to participate in the study.



The Family Educational Rights and Privacy Act (FERPA) is a Federal law that protects the privacy of student education records. FERPA applies to schools that receive funds under any program administered by the Secretary of Education. This law applies to all schools that receive funds from the U.S. Department of Education... That means you! Most private and parochial schools do not receive such funds and are, therefore, not subject to FERPA.

The U.S. Department of Education just published new regulations that reassure school officials that the government will not second-guess their decisions to share information about students who may be at risk of harming themselves or others. The new rules were prompted by the April 2007 shootings at Virginia Tech. The new regulations represent the most comprehensive reworking of the Family Educational Rights and Privacy Act (FERPA) in two decades. As SS/HS grantees, you should have received this information via our listserv.

Further information can be found on the Department of Education's website.

Notes:

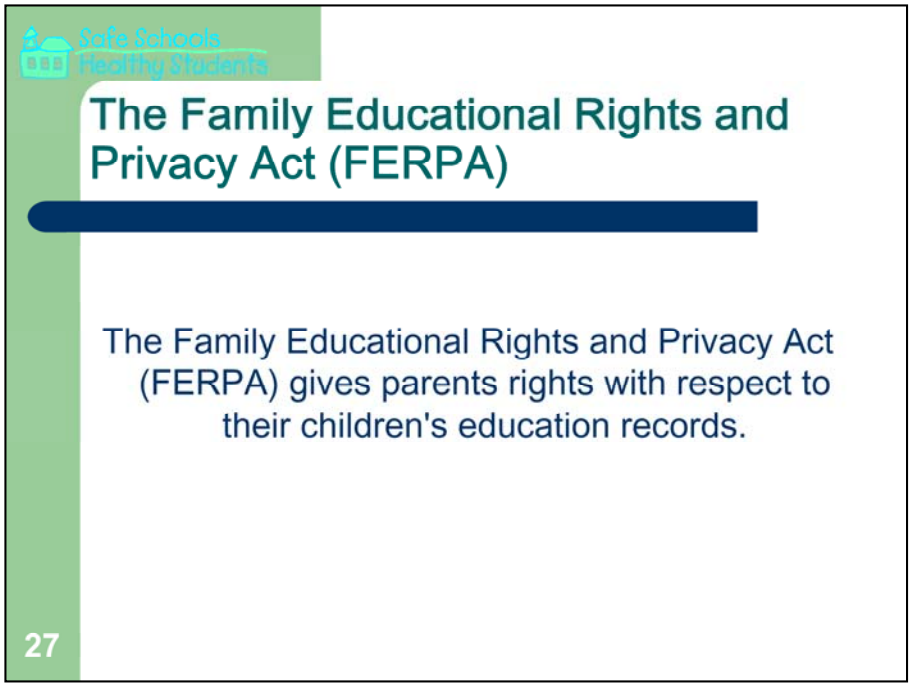
The U.S.Department of Education issued a press release announcing the publication, which you can access here on the Department's Web site:
http://www.ed.gov/news/pressreleases/2008/12/12092008b.html.

For the complete Federal Register Notice, visit:

http://www.ed.gov/legislation/FedRegister/finrule/2008-4/120908a.pdf.

These regulations are effective January 8, 2009.

U.S. ED's Family Policy Compliance Office hopes that you will find these regulations helpful. Should you have any questions about the issues raised in the final regulations, you may email them at FERPA@ED.Gov.

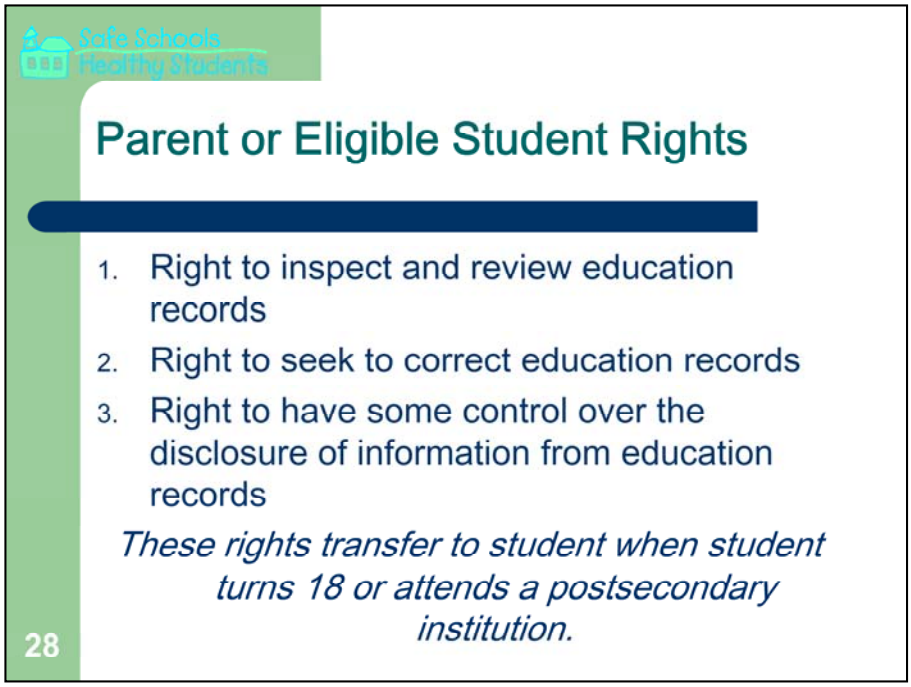


As I previously mentioned, the Family Educational Rights and Privacy Act (FERPA) gives parents rights with respect to their children's education records.

“Education records” are records that are –

(1) directly related to a student; and

(2) are maintained by an educational agency or institution or by a party acting for the agency or institution.

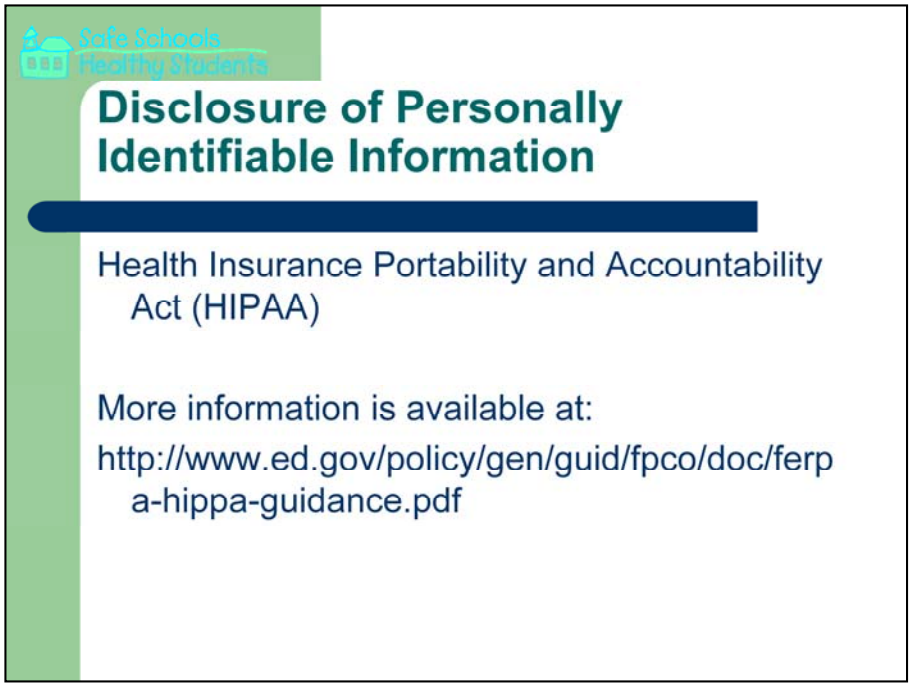


Primary Rights of Parents under FERPA include:

1. The right to inspect and review student education records maintained by school.
2. Right to request that a school correct records which they believe to be inaccurate or misleading.
3. And lastly, schools must have written permission from a parent in order to release information from a student's education record. This is the most likely point to pertain to SS/HS projects because many grantees want to use student information for planning evaluation activities.

You should also note that these rights transfer to the student when he or she reaches age 18 or attends a school beyond high school level. Students to whom rights have transferred are called "eligible students".

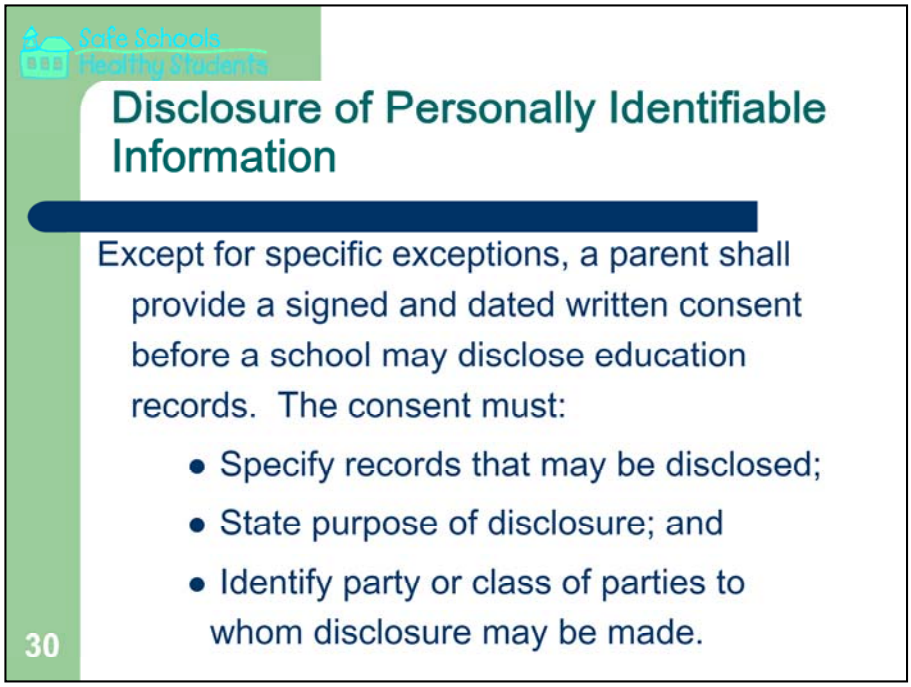
You should refer to your district's policy for rights of "eligible students". It's likely the school district has a policy in place regarding student – and parent – rights.



I want to touch briefly on the issue of disclosing health information and bring your attention to the Health Insurance Portability and Accountability Act of 1996, or HIPAA. Among other things, certain provisions of HIPPA address the security and privacy of health data. Our two partnering agencies: the Dept of Education and HHS, recently issued detailed guidance about the intersection between and requirements of FERPA and HIPAA. The guidance addresses the interplay between FERPA and the HIPAA Privacy Rule and many of the questions raised by school officials, health care professionals, and others regarding the applicability of these two laws to records maintained on students. It also addresses certain disclosures that are allowed without consent or authorization under both laws, especially those related to health and safety emergency situations. This information, titled: Joint Guidance on the Application of (FERPA) And (HIPAA) To Student Health Records will be posted on line with this PowerPoint presentation. You can also find the guidance on the Dept of Education's Web site (http://www.ed.gov/policy/gen/guid/fpco/doc/ferpa-hippa-guidance.pdf).

Your FPO is also available to field questions about disclosing health information as it relates to SS/HS; but an in depth discussion is outside the scope of today's presentation.

Understanding these laws will empower school officials to act quickly and decisively when problems arise.



Now back to FERPA…

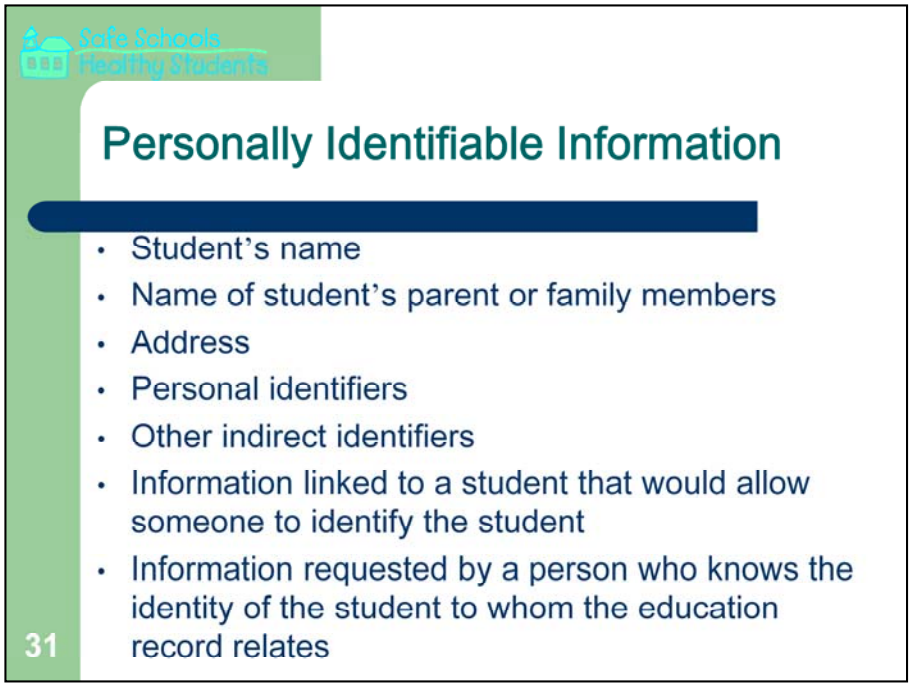
The FERPA disclosure requirements state that a parent shall provide a signed and dated written consent before a school may disclose education records.

The consent must:

Specify records that may be disclosed;

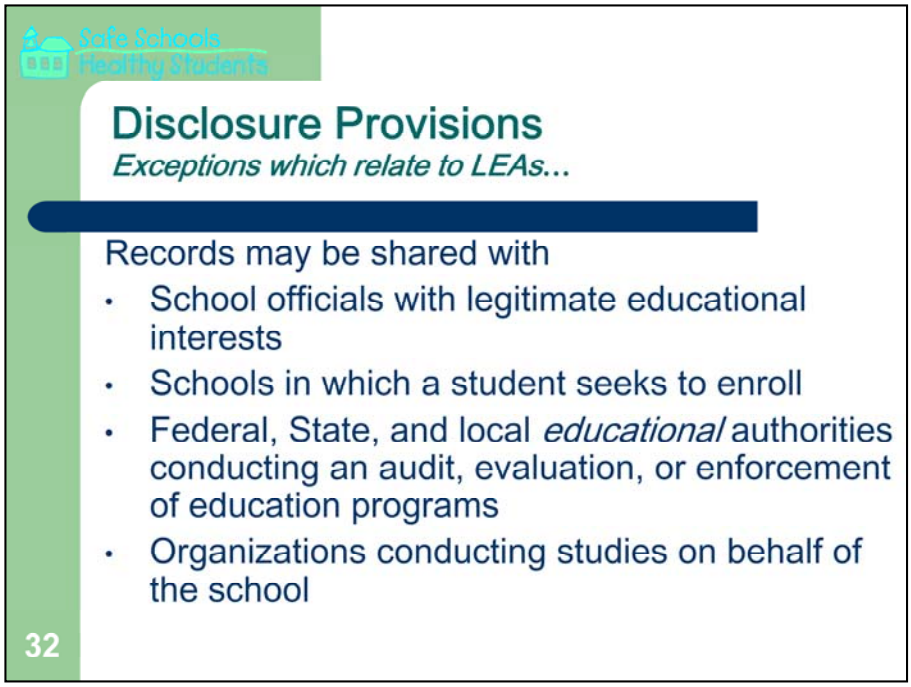
State purpose of disclosure; and

Identify party or class of parties to whom disclosure may be made.



Personally identifiable information includes, but is not limited to:

1. The student's name.
2. Name of the student's parent or other family members.
3. Address of the student or student's family.
4. A personal identifier, such as a social security number or student number.
5. Other indirect identifiers, such as date of birth or mother's maiden name.
6. Other information that, alone or in combination, is linked or linkable to a specific student that would allow someone in the school community to identify the student with reasonable certainty.
7. Information requested by a person who the institution believes knows the identity of the student to whom the education record relates.



Here are some of the conditions or exceptions which relate to LEAs in which prior consent is not required.

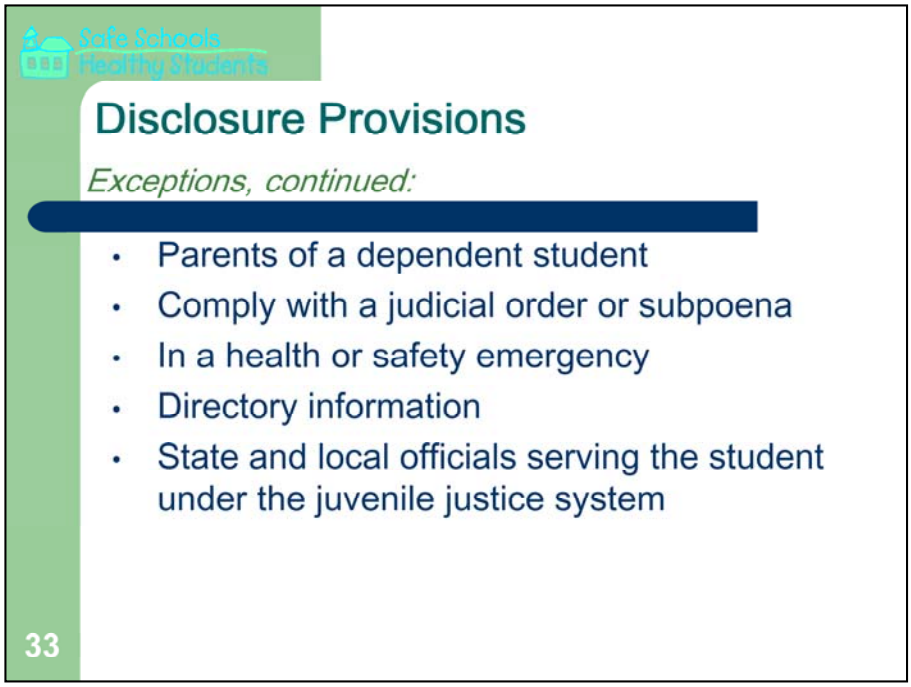
These exceptions include:

School officials with legitimate educational interests

Schools in which a student seeks or intends to enroll

Federal, State, and local educational authorities conducting an audit, evaluation, or enforcement of education programs

Organizations conducting studies on behalf of the school (as long as the information is de-identified)



Exceptions, continued:

Parents of a dependent student

In order to comply with a judicial order or subpoena (reasonable effort to notify)

In a health or safety emergency

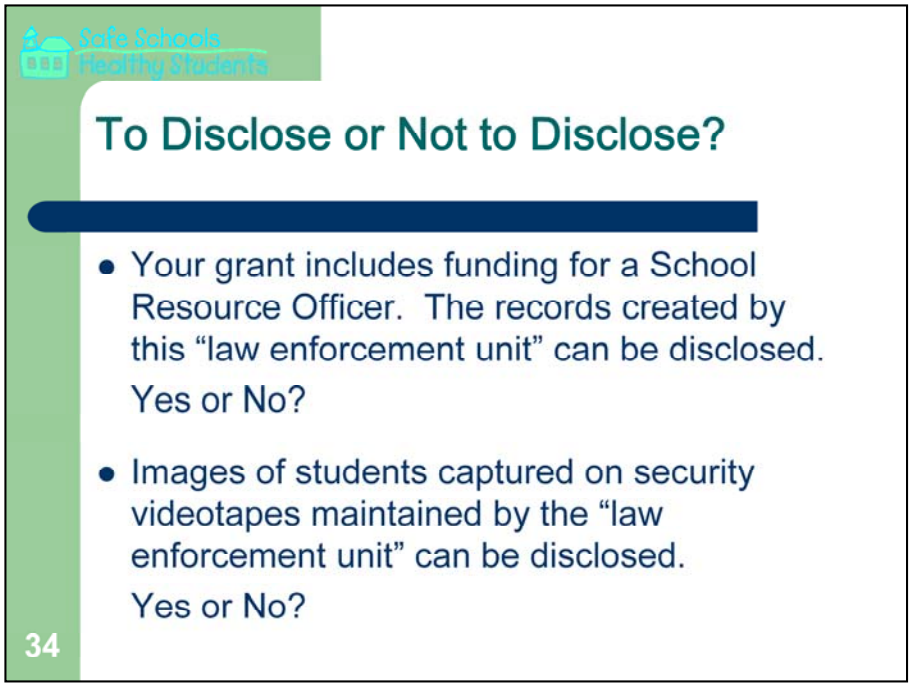
Directory information

To State and local officials serving the student under the juvenile justice system.

FERPA allows schools to disclose records, without consent, to certain parties under specific conditions. Of the exceptions I've listed, two are of particular note to SS/HS grantees are:

* Organizations conducting certain studies for or on behalf of the school provided there is no personally identifiable information – like your local evaluator or the National Evaluation Team; and

* State and local authorities, within a juvenile justice system, pursuant to specific State law.



Quick Test:

To disclose or not to disclose – that is the question.

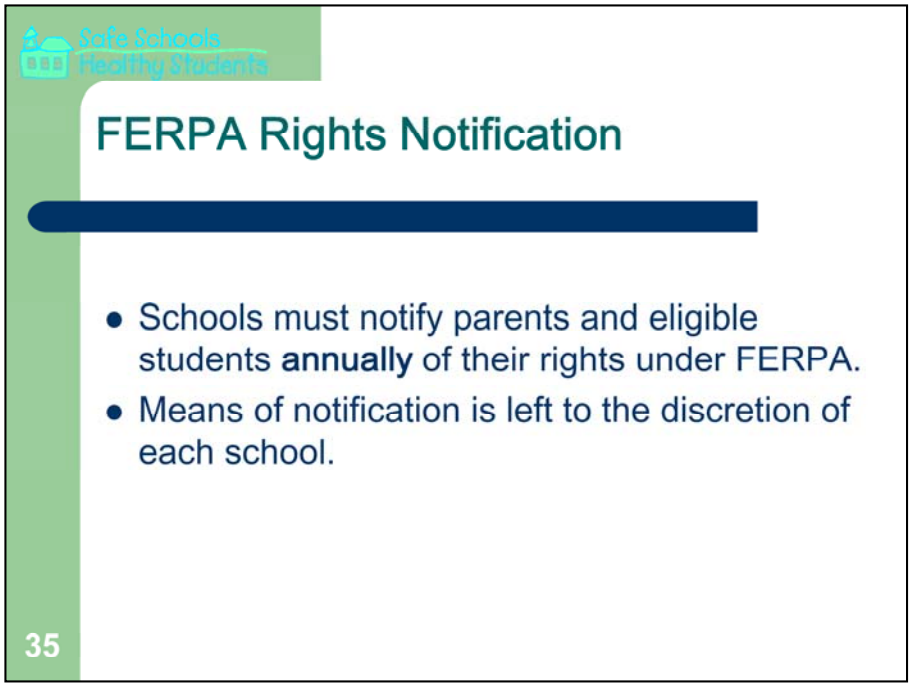
I am going to list a few conditions and want you to determine whether prior consent is required to disclose information.

1. Your grant includes funding for a School Resource Officer. Can the records created by this "law enforcement unit" be disclosed. Yes or No?

Yes. The School Resource Officer's records are not considered educational records and are not subject to FERPA. Schools may disclose law enforcement unit records without parental consent. Likewise, School Resource Officers may be given access to personally identifiable information from students' education records. An important caveat here is that the School Resource Officer's can not re-disclose this information.

2. Can images of students captured on security videotapes maintained by the "law enforcement unit" be disclosed? Yes or No?

Yes. These videos are not considered educational records under FERPA and may be shared with parents who's children are depicted in the video or with outside law enforcement authorities.



Schools must annually notify parents of students of their rights under FERPA, including:

Right to inspect and review education records;

Right to request amendment of education records;

Right to consent to disclosures, with certain exceptions; and

Right to file a complaint with U.S. Department of Education.

The means of notification is left to the discretion of each school. FERPA does not specify the means of notification, other than by any means reasonably likely to inform the parents. Examples include:

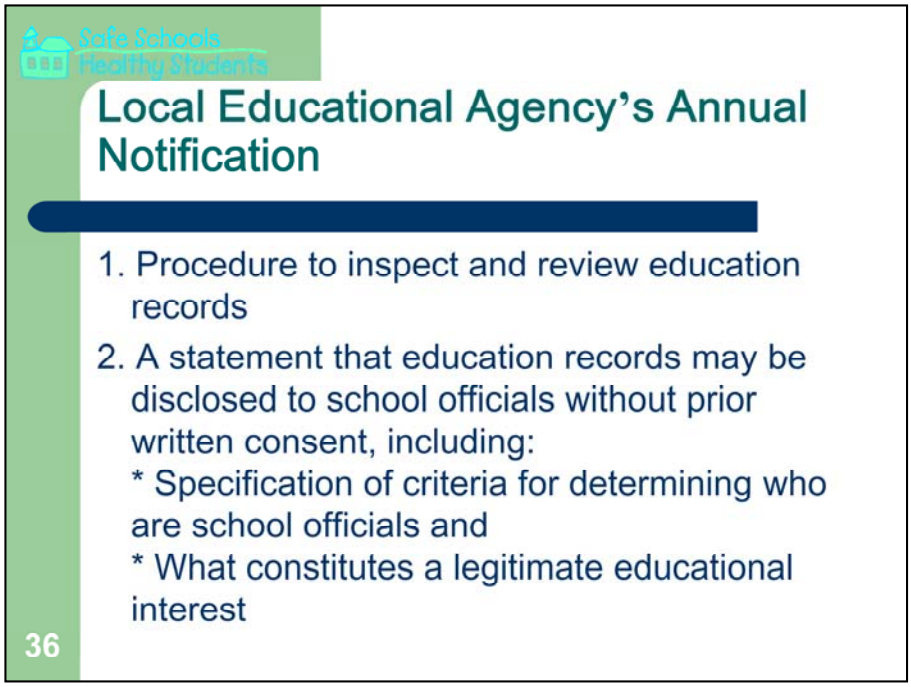
Student handbook

School newspaper or catalog

Local newspaper

Inclusion in student's registration packet

Likely, this is already taking place in your school district. However, it is helpful to know how and when for your SS/HS files.

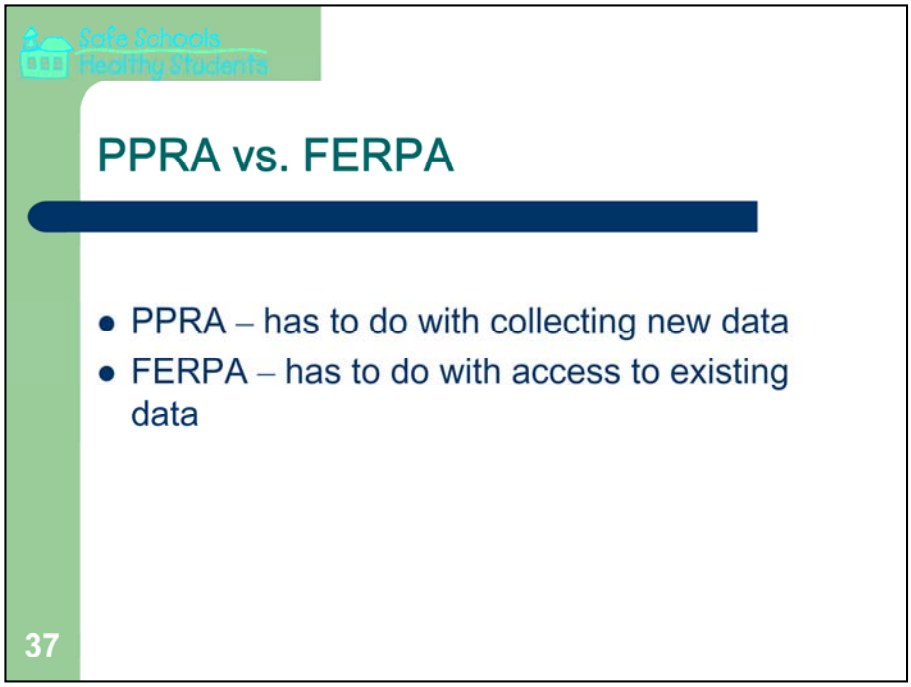


The LEA's annual notification to parents must also include the following:

A procedure to inspect and review education records; and

A statement that education records may be disclosed to school officials without prior written consent. This statement needs to include:

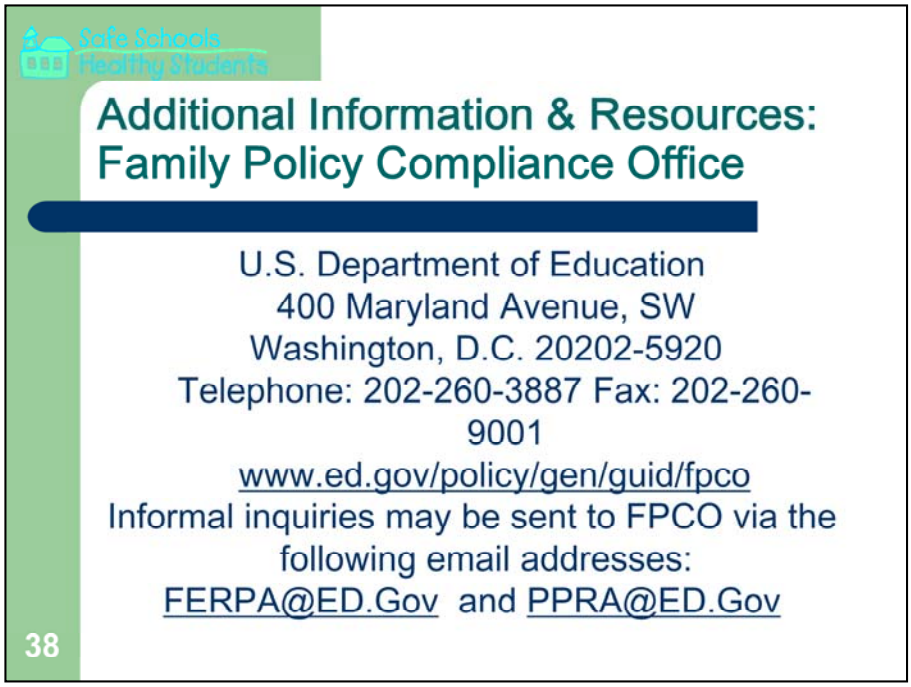
- Specific criteria for determining 'who are school officials' and
- What constitutes a legitimate educational interest.



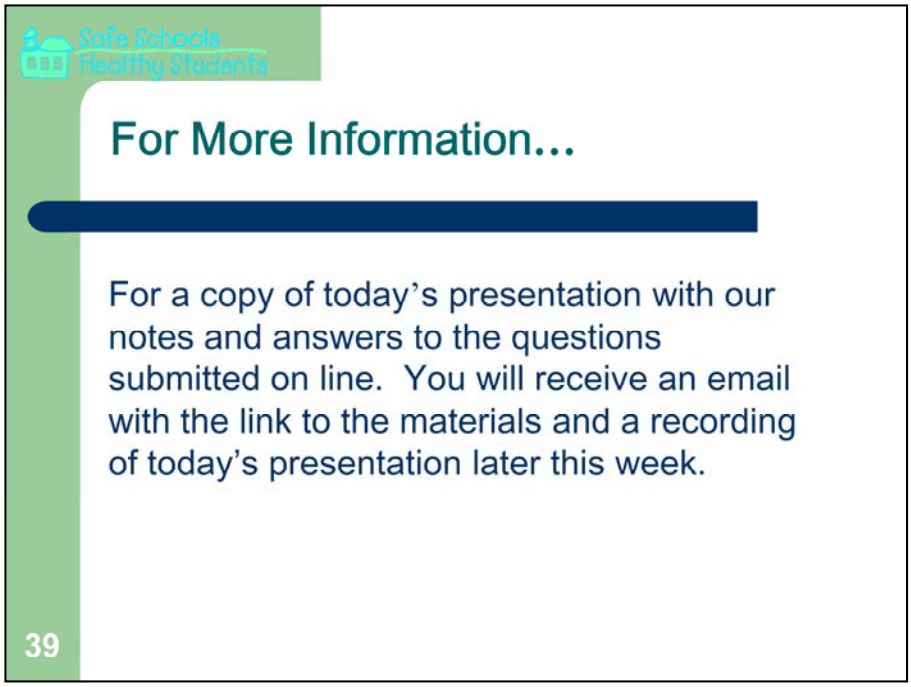
Just to be clear, the difference between the Protection of Pupil Rights Amendment and the Family Educational Rights and Privacy Act is that:

PPRA – has to do with collecting new data; and

FERPA – has to do with access to existing data.



For additional information about these policies, you can contact the Family Policy Compliance Office at the U.S. Department of Education.



For a copy of today's presentation - including our notes - and answers to the questions you've submitted, please visit us on-line. Now we will open it up for remaining questions and for any we don't get to today, we will either post the answers on-line or follow-up with you individually.

Please remember if you have a site specific question, we invite you to contact your FPO and they will work with you directly.

Thank you for your participation in today's webinar, we hope you found it informative and helpful.