I. Overview
Human subjects research funded by the U.S. Department of Education (DOE) or the National Institute on Disability and Rehabilitation Research (NIDRR) must comply with additional requirements in order to be approved by the VDSS IRB.

II. Regulatory Requirements:
34 CFR 97 Protection of Human Subjects
34 CFR 97 Subpart D Additional Protections for Children
34 CFR 350, 356 Disability and Rehabilitation Research
34 CFR 98 Protection of Pupil Rights (PPRA)
34 CFR 99 Family Educational Rights and Privacy Act (FERPA)

III. Scope of Guidance Document
This Guidance Document applies to all on-going and future human subjects research activities conducted or authorized by VDSS, local departments of social services, VDSS-licensed facilities, or VDSS-authorized contractors.

IV. Specific Additional Requirements
In addition to the requirements specified in 45 CFR 46, the VDSS IRB must consider the following requirements when reviewing non-exempt human subjects research.

A. Cooperative Research [34 CFR 97.114] - Cooperating institutions may only rely upon the review of another qualified IRB with the approval of the federal department or agency head. VDSS may rely on a collaborating institution’s IRB and vice versa only when the federal department or agency head has approved the reliance.

B. Research Involving Disabled Subjects [34 CFR 350.4(c)(1)] - When the research is sponsored by the National Institute on Disability and Rehabilitation and when children with disabilities or persons with mental disabilities are purposely included as research subjects, IRB membership must include at least one person who is primarily concerned with the welfare of these subjects.

C. FERPA: Use of Educational Records - Access to educational records is regulated by the Family Educational Rights and Privacy Act (FERPA), which stipulates generally that schools must have written permission from the parent or eligible student in order to release any information from a student’s education record.

   1. Researchers wishing to obtain data from educational records for the purposes of research are generally limited to the following options:
      a. Directory information - Schools may disclose, without parental permission, directory information such as student name, address,
telephone number, data and place of birth, honors and awards, and dates of attendance. Parents and eligible students can elect to restrict access to student directory information.

**b. De-identified information** - A school official with legitimate access (other than the researcher) may strip the records of any identifying information and provide the data to the researcher. De-identified records may not include any of the following personal identifiers:

1) Student’s name and other direct personal identifiers such as the student’s social security number or student number.

2) Indirect identifiers such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable, date and place of birth, and mother’s maiden name.

3) Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.

4) Other information that, alone or in combination, is linked to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

**c. Written, Informed Consent** - Parents or eligible students may be approached to provide signed informed consent. The consent must specify:

1) The records to be released

2) Reasons for the release

3) Parties to whom records may be released

4) Notice that, upon parental or adult student request, the school will provide her/him with a copy of the records disclosed

5) Notice that, upon parental request, the school will provide the student with a copy of the records disclosed

**d. Disclosure to other school officials whom the school has determined to have a “legitimate educational interest”** [34 CFR 99.31(a)(1)] - In these instances, the school must determine that the records being disclosed will be for a “legitimate educational interest,” including the specific educational interests of the child. A FERPA exception letter from the school is required to be submitted with the IRB application to document that the school has determined the use is allowable. In a K-12 school setting, this letter should typically come from the school superintendent. In a
e. Research conducted for or on behalf of the school [34 CFR 99.31(a)(7)] - Educational records may be released to organizations conducting studies for, or on behalf of, educational agencies or institutions for the purpose of developing, validating, or administering predictive tests, administering student aid programs, and improving instruction if the following apply:

1) The study is conducted in a manner that does not permit personal identification of parents and students by individuals other than representatives of the organization that have legitimate interests in the information;
2) The information is destroyed when no longer needed for the purposes for which the study was conducted;
3) The school district or postsecondary institution enters into a written agreement with the organization that:
   a) Specifies the determination of the exception
   b) Specifies the purpose, scope, and duration of the study and the information to be disclosed
   c) Requires the organization to use personally identifiable information from education records only to meet the purpose of the study as stated in the written agreement, and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information
   d) Requires the organization to conduct the study in a manner that does not permit personal identification of parents and students by anyone other than the representatives of the organization with legitimate interests
   e) Requires the organization to destroy or return to the school all personally identifiable information when the information is no longer needed for the purposes for which the study was conducted and specifies the time period in which the information must be returned or destroyed.

D. PPRA: Protection of Students [34 CFR 98] - The Protection of Pupil Rights Amendment (PPRA) applies to programs that receive funding from the DOE and is intended to protect the rights of parents and students in two ways (surveying students and psychiatric/psychological examinations):

1. Surveying Students - PPRA prohibits conducting required surveys of students without obtaining signed informed parental permission or signed consent from eligible students when any of the following topics are addressed in the survey material:
a. Political affiliations or beliefs of the student or the student’s parent
b. Mental or psychological problems of the student or the student’s family
c. Sex behavior or attitudes
d. Illegal, anti-social, self-incriminating, or demeaning behavior
e. Critical appraisals of other individuals with whom respondents have a close family relationship
f. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers
g. Religious practices, affiliations or beliefs of the student’s parent
h. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

Even when signed parental permission is obtained, this type of confidential information should be collected and maintained in secure environment.

2. **Psychiatric/Psychological Examinations** - No student shall be required, as part of any research project, to submit without prior consent to psychiatric examination, testing, or treatment or psychological examination, testing, or treatment.

3. **Instructional Materials** - When research will be conducted within a school, the school has policies addressing all of the following items. Documentation of the school policy must be provided to the IRB with the IRB submission and should address:
   a. Upon request, parents/guardians have the right to inspect instructional material used as part of the student’s educational curriculum.
   b. The administration of physical examinations or screenings that the school or agency may administer to a student.
   c. Arrangements to protect student privacy in the event of the administration of a survey to students, including the right of parents to inspect, upon request, the survey, if the survey contains one or more of the eight items of information listed above under “surveying students”.
   d. Upon request, parents/guardians have the right to inspect a survey created by a third party before the survey is administered or distributed by a school to students.
   e. 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.
f. Upon request, parents/guardians have the right to inspect 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 should be granted within a reasonable period of time after the request is received.

g. 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.

h. 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.

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