INTEGREVIEW IRB

July 19, 2018

Principal Investigator: Russell M Gersten, Ph.D.
Sponsor: Institute of Education Sciences (IES)
Protocol Number: IKAN-GLoSS_ED-IES-17-C-0011
Study Title: "A Study of Reliability and Consequential Validity of a Mathematics Diagnostic Assessment System in Georgia"

Dear Dr. Gersten:

The above-referenced study meets the requirements for a research study that may be reviewed through expedited review procedures set forth in federal regulations. Therefore, utilizing the expedited review procedures, initial approval was granted on the above referenced date by **Karen Haslund, M.D.** for IntegReview on the initial review of the above-referenced study.

Approved:

Principal Investigator
Investigative site(s) as submitted with initial submission documents
Protocol Version received 7/11/2018
Parent Opt-In Informed Consent, English language, dated July 19, 2018 (refer to IntegReview modifications as reflected on the following document containing revision marks)
School Personnel Informed Consent, English language, dated July 19, 2018 (refer to IntegReview modifications as reflected on the following document containing revision marks)
Assent, English language, dated July 19, 2018 (refer to IntegReview modifications as reflected on the following document containing revision marks)

Recruiting/miscellaneous materials:

Two questionnaires
One survey

The reviewer has identified one of these four risk categories that applies to children:

☒ Clinical investigations not involving greater than minimal risk
☐ Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects
☐ Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition
☐ Clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

ASSENT REQUIREMENTS:
The reviewer requires assent be obtained from minor subjects, ages 7 and above. Minor subjects under 7 years of age may give assent, but are not required to do so.

IMPORTANT

- **The following changes in approved research may not be implemented until you have received approval from IntegReview <u>except</u> where necessary to eliminate apparent immediate hazards to the human subjects:**
  - **Protocol Amendments**
  - **Change in the Principal Investigator and/or Sub Principal Investigators (only if the Sub PI's will be performing study-related procedures that the PI is not qualified through expertise to perform)**
  - **Change in the address at the study site or the addition of a study site(s)**
- **Only Informed Consent documents <u>containing IntegReview's approval</u> stamp may be utilized:**
  - **There must be procedures in place to guarantee that consent has been voluntarily obtained and properly documented.**
  - **For participants that do not speak English, the informed consent document must be in a language understandable to them; Non-English speaking subjects may <u>not</u> be enrolled until the foreign language Informed Consent Document(s) has been approved by IntegReview.**
  - **Only IntegReview staff may initiate modifications to Informed Consent documents. The Informed Consent document will be maintained in our computer files, and IntegReview will make all revisions following IRB approval**.
  - **Any modifications made to informed consents without prior IRB approval will be considered non-compliance and subject to, but not limited to, full board review, FDA review, suspension and/or termination of IRB approval.**
- **Only recruiting materials <u>containing IntegReview's approval</u> stamp may be utilized. All audio/video recording(s) must be submitted for IRB approval prior to broadcast.**
- **Revision requests should be submitted on IntegReview's forms, which are available in IRBManager.**
- **Visit our Website at www.integreview.com for information on research regulations, reporting requirements, Sponsor training, Investigator and research personnel training, etc.**

IntegReview approval for this study expires **July 18, 2019**.

In order to obtain extended IRB approval, IntegReview must receive your form for continuing review two weeks prior to the IRB expiration date. Appropriate forms will be forwarded to you approximately four weeks prior to the approval expiration date. Should the study end before you receive notification, submit a Closure Notification form.

<u>REPORTING REQUIREMENTS</u>

To ensure compliance with the applicable federal regulations as well as International Conference on Harmonisation (ICH), E6: Good Clinical Practice: Consolidated Guideline, and/or IntegReview's requirements, notification of the following are required for review/approval:

- **Report immediately:**
  - Changes in research that were initiated <u>without</u> IRB review and approval to eliminate apparent immediate hazards to the human subjects to ensure the continued safety and welfare of subjects
  - Modifications to previously approved documents
  - Receipt of investigator/site 483, Determination letter or Warning letter

- If your license is suspended, revoked, placed on probation or restricted in any state or country
- Safety information that may help to provide additional protections for subject's safety and well-being, throughout the course of the study and after study completion.
- Communication of results from a research study to subjects when those results directly affect their safety or medical care
- Reports of pregnancy
- Data Monitoring Committee (DMC/DSMB) Reports

- **Report within 10 calendar days of discovery:**
  - Revisions to the report of prior investigations, as applicable
  - Unanticipated adverse device effects, as applicable
  - Non-compliance – Failure by an investigator and/or sponsor to follow IntegReview's requirements, applicable regulations or to protect human research subjects, including but not limited to the principles of the Belmont Report
  - Serious non-compliance issues - non-compliance as defined as above and as determined to be serious in a way that adversely affects the rights and welfare of human subjects following the investigation and review by the IRB
  - Continuing non-compliance issues – A pattern of repeated non-compliance or serious non-compliance as determined by the IRB
  - Significant deviations – Significant deviations are those that deviate from the approved protocol, informed consent process and affect or potentially affect the safety of subjects. IntegReview does not consider protocol deviations to be different from protocol violations.
  - Unanticipated problems should be reported regardless of whether they occur during the study, after the study completion, or after participant withdrawal or completion. Any unanticipated problems involving risks to human subjects or others that are (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; (2) related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures in the research); and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. Examples of problems or events that may meet the definition of unanticipated problems involving risk to subjects or others may include, but are not limited to the following:
    - Imminent threat of a reportable event that has not yet occurred
    - Information indicating a change to the risk/benefit ratio of the research
    - Death
    - Breach of confidentiality, including lost or stolen study documents/data
- **Report within 30 days of acquisition or discovery**
  - New or additional conflicts of interests
- **Submit prior to publication/distribution:**
  - Any modification(s) to the previously approved Informed Consent document
  - New and/or modifications to previously approved recruiting/miscellaneous materials to be seen or heard by subjects
- **Submit two weeks prior to IntegReview approval expiration date:**
  - Continuing review documents
- **Submit upon completion of the study (**that is when all data has been collected):
  - Notification of study closure

At its discretion, IntegReview IRB reserves the right to visit the study site.

IntegReview IRB is organized and operates in accordance with the applicable federal regulations, and ICH Guidelines for Good Clinical Practices, E6. In addition, Standard Operating Procedures have been created to ensure compliance with these regulations and guidelines.

If you have any questions regarding these procedures or if you wish to appeal the decision, you may address your comments to IntegReview. Your comments will be reviewed, discussed and you will receive a response after your request has been considered.

Failure to comply with the Code of Federal Regulations or the requirements or determinations of IntegReview IRB can result in suspension or termination of IntegReview approval.

Sincerely,

Lynn Goldman, MSHP, RD, LD, CCRP
Operations Manager