Institutional Review Board (IRB)
Protocol Attachment

MARIAN UNIVERSITY

Attachment 1: Research with Children

Date Submitted:	October 26, 2011		
Principal Investigator	Jenna Linskens	**Email Address**	jalinskens67@marianuniversity.edu
Co-Investigator (if applicable)	Malia Hoffmann	**Email Address**	mmhoffmann74@marianuniversity.edu

By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person under 18 years old to be a child.

The HHS regulations at 45 CFR part 46, subpart D permit IRBs to approve 1-3 categories of research involving children as subjects. Fourth category of research requires a special level of HHS review beyond that provided by the IRB.

For any research involving children, identify and explain which of the four categories of research apply to that study, if any.

1. ☒ Research not involving greater than minimal risk to the children.

To approve research in this category all of the conditions below must be satisfied. Please explain how each condition is met.

i. the research presents no greater than minimal risk to the children

To minimize the potential risk of loss of time and inconvenience, teachers will conduct quick and brief surveys that will only take 10-15 minutes, which will all be completed via Survey Monkey and will not require any identifiers. Surveys sent to parents, teachers that are not participating, administraiton, and the community will not have any identiifers attached to them - they will also take approximately 15 minutes.

To minimimize potential risk of loss of time and inconvenience to the high school students and teachers, journal entries can be brief and should take no more than 5-10 minutes to complete daily.

To minimize the potential risk of emotional discomfort or distress, the participants will be told that they may choose to skip any question that causes them discomfort or stop the survey at any time. To minimize the potential risk of emotional discomfort or distress to the High School students and teachers involved, they will be told that they can leave out any information from the journal that makes them feel uncomfortable.

To minimize the breach of confidentiality, the teachers will only report the aggregate data of chapter / unit test scores, and WKCE test scores to the researchers. Names and personal identifiers will be removed prior to any information given to the researchers. All surveys completed via Survey Monkey will be annonymous and data will be kept on a secured computer. To minimize the break of confidentiality, the high school students and teachers will be given an identifier code (Teacher A, B, etc. and Student A, B, etc.) and the master list will be kept separate in a locked cabinet at the Appleton campus. To minimize the breach of confidentiality for community members / visitors, the survey will not ask for any identifying information and a locked box will be kept in the school office for completed surveys to be dropped off. The box will be given to the researchers for removal of the surveys.

; *and*

ii. adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

In Fall 2011, Aaron Sadoff will release information on the iPad study to the faculty in NFDL. Educator applications will be disributed asking for participation in the study. Two educators from the elementary school that teach the same grade level will be choosen to allow for a study and control group. One teacher from the middle school that teaches the same subject / level four times a day will be choosen to allow for 2 study and 2 control groups. 10 high school students of the same grade level will be randomly choosen to participate. All participants will be asked to participate in the study via a formal anouncement from Aaron Sadoff, Superintendant. The classroom teachers who have been chosen to participate will obtain written assent from the students via letters home to the parents, seeking first parental consent and assent, and then student assent. Aaron Sadoff will meet with the 10 high school students and provide them with letters to go home seeking first parental consent & assent and then student assent. Teachers, parents, and community members not identified to participate will be encouraged to observe the classrooms both using and not using the iPads, via a formal media announcement from Aaron Sadoff. Those who chose to observe will be given the opportunity to complete an Annonymous survey of their observations.

Institutional Review Board (IRB)
Protocol Attachment

MARIAN UNIVERSITY

After receiving IRB approval, professors Jenna Linskens & Malia Hoffmann will give all of the consent / assent forms to Aaron Sadoff for disbursement to the teachers that have chosen to participate in the study. The classroom teachers will obtain consent from parents and assent from students. The high school principal and Aaron Sadoff will obtain parental consent from the High school students' parents and then obtain assent from the students. The classroom teachers and Aaron Sadoff will obtain adult assent. This will all occur after IRB approval.

After receiving IRB approval, the reserchers will send all consent forms to Aaron Sadoff for disbursement and collection. Parent consent / Adult consent (parents & teachers) forms will be obtained prior to obtaining child (students) assent via the classroom teachers. Teachers will send home Parent Consent & Adult Assent forms via postal mail once IRB approval is given. After parent consent has been given, the teachers and high school prinicipal will obtain student assent via face-to-face / classroom meetings. Community / Visitor surveys will have a statement of assent listed at the top of the survey page, but will not ask for any indentifying information.

2. ☐ Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research. (Note: signatures of both parents *may* be required.)

   To approve research in this category all of the conditions below must be satisfied. Please explain how each condition is met.

   i. the risk is justified by the anticipated benefits to the subjects;

   ii. the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches;
   ; *and*

   iii. adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

3. ☐ Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition. (Note: signature of both parents *will* be required.)

   In order to approve research in this category, all of the conditions must be satisfied. Please explain how each condition is met.

   iv. the risk of the research represents a minor increase over minimal risk;

   v. the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;

   vi. the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition;
   ; *and*

   vii. adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408. the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

4. ☐ This research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Research falling into this category can be approved only after the Secretary of Health and Human Services (HHS), in consultation with a panel of experts, determines that the research satisfies applicable conditions under §46.407.

Last Update: July 2009