**Instructions**: In order to review research with human subjects, the Marian IRB requires the completion and submission of the Protocol Submission Form as well as all appropriate supplementary material. Please note that additional explanations can be found by clicking on bolded words or at <http://www.marianuniversity.edu/irb>. Each Section must be completed unless directed otherwise. Incomplete forms will delay the IRB review process and may be returned to you. Enter your information in the shaded boxes; the boxes will expand as you type.

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| **Section A: General Information** | | | |
| **1. Principal Investigator** |  | **Department** |  |
| **Email Address** |  | **Telephone** |  |
| [**Human Subjects Training Courses Completed**](http://www.marianuniversity.edu/interior.aspx?id=8190) | If Other\*:  \*must be approved by the IRB; please attach documentation of completion | | **Completion Date**  Month  Year |
| **2. Co-Investigator or Research Advisor (if applicable)** | Aida Nichlowski, PhD, JD | **Department Institutional Affiliation**  *(If other than Marian University)* | School of Education  C & I |
| **Email Address** | amichlowski@marianuniversity.edu | **Telephone** | 923-8749 |
| [**Human Subjects Training Courses Completed**](http://www.marianuniversity.edu/interior.aspx?id=8190) | If Other\*: IRB member  \*must be approved by the IRB; please attach documentation of completion | | **Completion Date**  Month November  Year 2008 |
| **3. Study Title (not the research question)** | example: Moltivating Students to Read the Kindle Way | | |
| **Dates of Project** | **Start Date:** *From IRB approval to* | **Proposed End Date:**  08/01/10  (mm/dd/yy) | |
| **Purpose of project** | If other, please specify: | | |
| **4a. Conflict of Interest:** Does the researcher or key personnel have a potential financial conflict of interest in this study that should be disclosed?  **If Yes,** Please explain: | | |  |
| **4b.** Does the researcher or key personnel have a potential conflict of interest due to the nature of the relationship between the researcher and any cooperating agency or organization involved?  **If Yes,** Please choose one (if appropriate) or explain: or | | |  |
| **4c.** Does the researcher or key personnel have a potential conflict of interest due to the nature of the relationship between the researcher and the potential participant?  **If Yes,** Please choose one (if appropriate) or explain: or | | |  |
| **5. Research Location:** Where will the research be performed?  (if not on campus, please provide the full address; if online, please indicate online address)  *If the research will be conducted in a school, institution, or facility other than Marian University, include a signed letter of permission, on letterhead stationery, from that institution and/or its IRB. This letter must be received by the ORSP prior to IRB approval. A Site Permission Letter template is available on the ORSP website.* | | | School Mailing Address |
| **6. Does the research require another IRB review?**  **If Yes,** Please provide the following details: Name of IRB:  Contact Information:      ; FWA # (or equivalent):  PI must provide the Marian IRB with the completed application for the other IRB’s and documentation of approval. | | |  |

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| **Section B: IRB Review Determination** | | | | | | | |
| 1. Is the study intended or expected to result in publication, presentation outside the university classroom, or public dissemination in some other form? (e.g. websites, journals, newspapers, conference presentation, McNair scholar presentation, deposited in library, etc.) | | | | | |  | |
| 2. Are you requesting an **exemption** from federal regulations in your IRB review? | | | | | |  | |
| *If yes, please select the appropriate* [*category(ies)*](http://www.marianuniversity.edu/interior.aspx?id=10334#Categories)*.* | 1 | 2 | 3 | 4 | 5 | | 6 |

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| **Section C: Human Participant Population** | | | | |
| 1. Approximate number of participants: | 30 | | | | |
| 1. Age   *Check all that apply* | Birth to 3 years (Parent permission document required) | | | | |
| 4-5 years ( Parent permission document & child’s assent script required) | | | | |
| 6-17 years (Parent permission document & child’s written assent required) | | | | |
| 18 years & older (Written Consent document required) | | | | |
| 1. Populations   *Check all that apply* | Children (minors under 18 yrs.) *(Complete Attachment 1 and submit with application)* | | | | |
| Males | Females | College Students | Ethnic groups | |
| Terminally ill | | HIV/AIDS patients | Non-English speaking | |
| Neonates / Fetuses | | Pregnant Women | Native American Tribes | |
| Substance abusers | | Crime victims | Institutionalized individuals | |
| Prisoners *(Attachment 2 required)* | | | Decisionally impaired | |
| Persons living outside the U.S. | | | Other: | |

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| **Section D: Study Description** |
| *Provide a brief summary of the proposed research. Focus your answers on the involvement and treatment of human participants. Use simple language; avoid technical terms and abbreviations. IRB members not familiar with the area of research must understand the nature of the research. Please also use spell-check to ensure proper spelling and grammar.* |
| 1. Brief **(300 WORDS OR LESS)** summary of research study: 2. Purpose of Research To investigate the effect of using iPads or Kindle on students' reading level and motivation. 3. Procedures 4. Research design  combination qualitative and quantitative 5. Method of collecting data  pre and post survey (attached questionnaire), pre and post test (attached), anecdotal logs or observation notes (attached form) 6. Participant Withdrawal (Describe methods if the participant wishes to withdraw from the study ) Should a participant decide to withdraw from the study, all the data pertaining to that student will be destroyed and will not be included in the analysis. 7. Data Analysis (Discuss means of organizing and analyzing the research data; include steps taken to ensure confidentiality)   Data from test scores will be coded and only summary results such as means will be reported. Responses from survey will be anonymous. Data will be analyzed to find central tendencies and patterns only. |
| 1. Reporting Procedures: Identify the audience to be reached in the report of the study, presentation method, and feedback to the participants.   The final research paper will be submitted to the action research instructor/co-investigator and archived. The aggregated data and summary results will be shared with the school principal, district administrator, staff, department or unit members at a unit or staff meeting or a staff development session. The summary results of this study will also be shared with students, their parents and other stakeholders upon request. The researcher may, in the future, write an article for publication based on this study. |

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| **Section E: Data Collection Methods** | | | |
| *Check all method(s) to be used. Submit copies of all surveys, questionnaires, interviews, and focus group scripts.* | | | |
| 1. Survey/Questionnaire   *(Includes pre/post tests, etc.)* | Phone | In-person | Internet |
| Email | Postal Mail | Other: |
| 1. Interview | One-on-one | Focus Group | Oral History |
| Other: | | |
| 1. Observation of Public Behavior | Classroom | Public Meeting | Other: pre and posttests |
| 1. Examination of Archived Data/Secondary or Records | Briefly describe: examples: attendance records, test scores from previous years e.g. WKCE, MAP, chapter tests | | |
| 1. Taste Evaluation | Food Tasting | Non-wholesome Food | Genetically Altered Food |
| 1. Examination of Human Pathological or Diagnostic Tissue Specimens (ex. Blood, bodily fluids) | | | |
| 1. Experimental (unproven or untested procedures) | Biomedical | Psychological | Other: |
| 1. Voice/Video/Digital/Image   *(Note: Confidentiality agreement may be required for transcription, translation and project personnel)* | Voice | Video | Digital |
| Image | Other: | |
| 1. Other: | | | |

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| **Section F: Confidentiality and Protection of Data** | | | | | | |
| 1. Level of confidentiality and identification at each phase of the project   Anonymous: No identifiers that link the data to a specific participant  Confidential - Coded: Collected with identifier, but all identifiers & codes are removed  Confidential - Unlinked: Linked to a specific participant by a code, not by a direct identifier  Intentionally Identified: Linked to a specific participant by personal identifiers  Combination: More than one level of confidentiality and identification for any one phase of the project | | | Data Collection | |  | |
| Data Storage | |  | |
| Data Analysis | |  | |
| Data Dissemination | |  | |
| 1. Methods of data protection   Check all that apply. | Locked Cabinet | Locked Office | | Firewall System | | Encrypted Data |
| Coded to a Master List | Restricted Computer | | Other: | | |
| 1. Location of data | Address: your office address | | | Room #: T323 | | |
| 1. Will master list be kept separate from the data? |  | | | | | |
| 1. When will all research materials be destroyed, including voice/video/digital/ image? | December 2013 | | | | | |
| **NOTE: Research materials MUST be kept for a minimum of 3 years after completion of study.** | | | | | | |

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| **Section G: Human Participant Recruitment** | | | | |
| 1. How will potential participants be identified? How will potential participants be approached?   (Explain in detail) | All students currently attending the researcher's Reading class will be invited. Of those who agree to participate, groups will be randomly selected and assigned. | | | |
| 1. Who will obtain consent/ assent and when will that be done? | The principal investigator wil obtain the parental consent and student assent after IRB approval., | | | |
| 1. What recruitment/advertising methods will be used?   Check all that apply and attach materials. | None | Phone | E-mail | Postal mail |
| Person -to- Person solicitation | Media  (TV, newspaper, radio, website) | Other: | |
| 1. Will participants be compensated (extra credit, money, gift certificate, etc.)?   *NOTE: If students are recruited from MU classes and will be receiving extra credit for participation, they must be able to complete an alternative assignment for extra credit should they choose not to participate. This assignment must be comparable, with respect to time and effort, to participation in the research.* |  | | | |
| *If Yes,* | | | |
| 1. what is the compensation? | |  | |
| 1. how much will they be offered? | |  | |
| 1. how will they receive it? | |  | |
| 1. when will the participants be compensated? | | Before the study  Installments during the study  Upon study completion | |
| 1. Are you purposely excluding groups of people? |  | | | |
| If yes, which groups are being excluded? | |  | |
| Explain the reasons for the exclusion criteria. | |  | |

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| **Section H: Informed Consent/Assent/Parent Permission** | | | | |
| 1. What type of consent will be used?   *Attach a copy of the consent document(s). Consult the ORSP website for the consent form checklist and recommended templates.* | Written Consent | Online Consent | Oral Consent | |
| Information Sheet | Guardian Permission & Adult Assent | Parent Permission & Child Assent | |
| Waiver (see below) | Other: | | |
| If you are requesting a waiver of informed consent, you must demonstrate that:   * 1. The research involves no more than minimal risk to the participants;   2. The waiver will not adversely affect the rights and welfare of the participants;   3. The research could not practicably be carried out without the waiver; and   4. Whenever appropriate, participants will be provided with additional pertinent information after participation.   Considering the above requirements for a waiver of informed consent, please describe how your research qualifies for this waiver***:***  *If you are requesting a waiver of documentation of informed consent process, complete Attachment 3 and submit with application* | | | |
| 1. Do you intend to use an informed consent document in a language other than English?   *If Yes, provide both the English and non-English versions* | | | |  |
| 1. Do you intend to use an oral consent?   *If Yes, describe the rationale and how you will document it.* | | | |  |
| 1. Describe your informed consent process in a step-by-step manner: | After receiving IRB approval, the researcher will send the adult consent (attached) home. After receiving the parent consent forms, students whose parents gave their consent, will be asked to complete the child assent forms (attached) in the classroom. | | | |

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| **Section I**: **Risk and Benefit Assessment** | | | |
| 1. What are the potential risks to participants?   Check all that apply. | Loss of time or inconvenience | Emotional discomfort or distress | |
| Breach of confidentiality | Physical harm or discomfort | |
| Legal | Social stigmatization | |
| Invasion of privacy to the participant or family | Withholding standard care and procedures | |
| Psychological effect that is more than discomfort or distress | Economic (e.g. employment, insurability) | |
| Activity that may be considered sensitive, offensive, threatening, or degrading to participant | Other: | |
| 1. What is the overall potential risk level on the items above in #1?   Choose one: | Not greater than minimal risk | | |
| Greater than minimal risk, but presenting the prospect of direct benefit to individual participants | | |
| Greater than minimal risk, no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition | | |
| Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of participants. | | |
| 1. How will you minimize these potential risks in order to protect participants’ rights and welfare? | To minimize the potential risk of loss of time and inconveniene, the researcher will be well-prepared, execute the plan efficiently, follow the usual classroom routines, conduct quick and brief quizzes or surveys that will only take 5-10 minutes.  To minimize the potential risk of loss of confidentiality, the surveys will be collected and placed in a secure location in a locked file drawer accessible only to the researcher. The student names will be removed from the surveys and a code (Student 1, Student 2, or Student A, Student B) will be used as an identifier.    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 withdraw from the study at any time.  All of the above will be explained in writing and orally in the student assent form. | | |
| 1. If any of these potential risks occur, how will it be handled (ex. counseling, etc)? | talk to the affected participants and their parents, offer counseling to the participant (s) start data collection over, etc. | | |
| 1. Is it possible that you will discover a participant’s previously unknown physical or psychological condition (e.g. disease, depression, suicidal ideation, genetic predisposition, etc.) as a result of your procedures? | | |  |
| 1. Does the study pose risk to individuals other than the participants? | | |  |
| 1. Describe the expected benefits of this project.   *Compensation is not considered a benefit.* | To the individual participants: The students will find the value of ebooks and hopefully get into the habit of reading. | | |
| To society: The society will benefit by a literate and informed citizenry. | | |
| 1. Explain how, in your assessment, benefits of this study outweigh the risks. | The information gathered is more valuable to the improvement of the educational setting, curriculum, practice. than the minimal risk involved | | |

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| **Section J**: **Potential Reportable Activities** | | |
| *The researcher has the legal obligation to disclose to the proper authorities certain information about reportable activities obtained during research. This obligation and intended course of action must be communicated to the participants in the consent form.* | | |
| 1. Will the project involve the potential discovery of these illegal or reportable activities? |  | *If Yes, check all that apply.* |
| Drug Use | Child Abuse |
| Alcohol Consumption by a Minor | Other Violations of Law: |

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| **Section K**: **Deception** | | | |
| 1. Will any information be purposely withheld from the participants or will they be given any misinformation? |  | *If Yes,* | |
| 1. why is the deception necessary? | |  |
| 1. how and when will the participants be debriefed after the project?   *(Also attach the debriefing script)* | |  |

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| **Section L**: **Protected Health Information (HIPAA)** | | |
| *If you answer No to all the questions below you are not subject to HIPAA. If Yes to any of the questions below, complete Attachment 4 and submit with application*. | | |
| 1. Will health information be obtained from a covered entity (a health care provider who bills health insurers)? | |  |
| 1. Does the research involve the provision of healthcare in a covered entity? | |  |
|  | *If Yes,* will a health insurer or billing agency be contacted for billing or eligibility? |  |
| 1. Does the research involve use or creation of protected health information? | |  |

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| **Section M**: **Other Information** | | | |
| 1. Will any investigational new drug (IND) be used? | |  | |
|  | *If yes, complete Attachment 5 and submit with application* | | |
| 1. Will any other drugs be used? | |  | |
| 1. Will any investigational device (IDE) be used? | |  | |
|  | *If yes, complete Attachment 6 and submit with application* | | |
| 1. Will alcohol be ingested by the participants? | |  | |
|  | *If yes,* describe what type and how it will be administered. | | |
| 1. Will blood, tissue, bodily fluids, or other biological specimens be collected? | |  | |
|  | *If yes,* will any of the blood, tissue, bodily fluids, or other biological specimens be used for genetic testing? *Attachment 7 must also be completed and submitted with application* |  |
| 1. Do your studies involve the analysis of genes known to be implicated in the disorder(s), syndrome(s) or condition(s) you are studying? | |  |
| 1. Do your studies involve finding the gene(s) that may cause the condition or genetic markers that cosegregate with this condition? | |  |
| 1. If samples are used, will they be used for any purpose other than to study genes related to the diseases discussed in the application and the consent form? | |  |
| 1. Will any electrical or mechanical systems that require direct human contact be used? (does not include use of computers for data keeping and surveys) | |  |
|  | If Yes, attach a copy of the manufacturer's electrical/mechanical safety specification information for each instrument/device. If the device is custom made, attach detailed description/information on design and safety with respect to human participants application. Also, please indicate the date of the last safety inspection for all electrical/mechanical devices, instruments, and systems you will use.  NOTE: Electrical and mechanical safety inspections must be performed and documented on an annual basis. Documentation of the most recent safety inspection must be submitted with the initial protocol submittal, as well as with any subsequent 3-year renewals. | |

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| ORSP USE ONLY: |
| Last Updated: 8/24/09 |

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| **Principal Investigator Assurances**   1. I certify that the information provided in this application, and in all attachments, is accurate and complete. 2. I understand that I have primary responsibility for the conduct of this study, the ethical performance of this research, and the protection of the rights and welfare of human participants. 3. I agree to adhere to the policies and procedures of Marian University IRB, the published guidelines for the ethical conduct of research in my field of inquiry, and the applicable local, state and federal regulations regarding the protection of human participants in research. 4. I certify that the equipment, facilities, and procedures to be used in this research meet recognized standards for safety. 5. I certify that unanticipated problems, adverse events, and new information that may affect the risk-benefit assessment for this research will be reported to the IRB Administrator at 920-923-8796 or [orsp@marianuniversity.edu](mailto:orsp@marianuniversity.edu) 6. I will notify the IRB of completion of the research or departure from the university. 7. I agree to maintain all records related to this project for at least three years after completion of the research project. 8. I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until written approval from the Marian University IRB has been obtained.   *If you should make any changes in the protocol involving 1) method, 2) participants, 3) informed consent, and/or 4) participant identification, you must resubmit the protocol. The case number assigned to this protocol will be included in your notification of protocol approval. Please reference this number in all future correspondence. You are responsible for submission of an Annual Progress Report if required by the IRB.*  Student Principal Investigators are required to submit this form electronically to their research advisor for final signoff. Non-student Marian Principal Investigators may submit this electronically from their Marian University email address to the ORSP (substitutes for handwritten signature). | | |
| Typed Name: | Signature:  Click here if submitted electronically | Date: |
| RESEARCH ADVISOR’s Assurances (mARIAN fACULTY OR sTAFF)  1. I certify that I have **read and approved** this IRB protocol and supporting materials. 2. I certify that the student researcher on this study has sufficient knowledge and experience to conduct the proposed research as outlined in this protocol. 3. I certify that I am familiar with the policies and procedures of the Marian IRB and published guidelines for the ethical conduct of research in my field of inquiry, 4. I agree to provide ongoing supervision of the student researcher and co-investigator(s), to approve and sign all communications with the IRB regarding this project, and to monitor the progress of this research. 5. I certify that the proposed research is not currently underway and will not begin until written approval from the Marian University IRB has been obtained.   Research advisors may submit this electronically from their Marian University email address to the ORSP (substitutes for handwritten signature). | | |
| Typed Name: Aïda Michlowski, PhD, JD | Signature:  Click here if submitted electronically | Date: August ?, 2010 |