IRB EXPEDITED OR FULL REVIEW APPLICATION

IRB No.: 14-114-MAR-XPD Rev. No./Date:

Submit all documents to IRB@uml.edu Date Submitted to IRB: 6/25/14

A. GENERAL INFORMATION

Project Title: Middle School Pathways in Computer Science	
PI: Fred Martin	Email: fredm@cs.uml.edu
Department: Computer Science	Work Address (Bldg and No.): Olsen 208
Phone: 978 934 1964	Emergency Phone: 508 662 7712
Co-PI(s): Diane Schilder (project evaluator)	Co-PI(s) Contact Info: dschilder@eval-inc.com

1. Sponsor Information-Check One

NOTE: PIs must notify the IRB immediately of any change in funding related to research activities that involve human participants and submit a copy of the final proposal submitted for funding to the IRB for review.

( ) Not funded.
( ) Internal funding. Type:
(X) Government/Federal funding. List agency name: NSF – award in process.
( ) Subcontract. List organization name and include contact name, telephone, and address:

( ) Other. List organization/company name and include contact name, telephone, and address:

If funded, has the proposal been submitted to the IRB? ( ) Yes ( ) No ( ) N/A

2. Project Personnel: Include the PI and all personnel who may interact with participants or access identifiable human participant data. Submit copies of the training certifications with the application.

Name and Title(Check one)	Email Address	Training Completed
Fred Martin (X) Faculty ( ) Staff ( ) Student	fredm@cs.uml.edu	(X) CITI Basic, Date: June 27, 2014 ( ) NIH, Date:
Diane Schilder ( ) Faculty (X) Consultant ( ) Student	dschilder@eval-inc.com	(X) CITI Basic, June 14, 2014 ( ) NIH, Date: enter date

Additional personnel or other information:

a. Is this a student research project? ( )Yes (X) No
If yes, ( ) Graduate or ( ) Undergraduate, please specify below:
( ) Dissertation ( ) Thesis ( ) Directed Study ( ) Class Project ( ) Other:

B. CATEGORY CLAIMED

( ) Request for Full IRB review (Research with prisoners REQUIRES Full Review.)

OR

(X) Request for Expedited Review-Research reviewed under this category must involve no more than minimal risk and be described by one or more of the allowed categories. Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 Code of Federal Regulations (CFR) 46.102(i)]. Check those that apply:

( ) **1**. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

( ) a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

( ) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

( ) **2**. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

( ) (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

( ) (b) From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

( ) **3**. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

( ) **4**. Collection of data through noninvasive procedures (not involving anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

( ) **5**. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4).

( ) **6**. Collection of data from voice, video, digital or image recordings made for research purposes.

(X) **7**. Research on group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identify, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. [NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3).]

( ) **8**. Continuing review of a previously approved protocol by a convened IRB. (Note: (If this applies, submit an Annual/Continuing Review form instead of this application.)

( ) **9**. Continuing review of research not conducted under an investigational new drug application or investigational drug exemption where categories 2 through 8 do not apply, but the IRB has determined at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. (Note: If this applies, submit an Annual/Continuing Review form instead of this application.)

C. OTHER REQUIRED INFORMATION

1. Conflict of Interest Disclosure:

a. Do you or any family members have a financial interest in this research activity (such as an equity position or outside consulting arrangement with the company whose drug, procedure, device or product is used or tested in this study)? ( )Yes (X) No

b. Do other faculty or staff involved with this research have a financial interest in this research activity? ( )Yes (X) No

c. To your knowledge, does the University have a financial interest in the company whose drug, procedure, device or product is used or tested in this study (such as patent rights, equity)? ( )Yes (X)No

If yes, indicate the nature of the relationship and the conflict(s):

2. Is an investigational drug, biologic, or device proposed for use with participants in this study? ( ) Yes (X) No

a. If yes, an application must be submitted to the U.S. Food and Drug Administration for an Investigational Device Exemption (IDE) or Investigational New Drug (IND) authorization. Provide a copy of these materials to the IRB for review.

3. Does the research require any other committee review? ( )Yes (X) No

( ) IBC for use of biohazardous materials (blood, tissue, serum, etc.)
Indicate status: ( ) Registration Approved, IBC No. or ( )Registration Pending

( ) IACUC for using Animal Models
Indicate status: ( ) Protocol Approved, IACUC No. or ( )Protocol Pending

( ) Stem Cell Research, IRB Subcommittee

4. Are you working with a researcher from an institution with their own IRB? ( ) Yes (X) No
If yes, do you intend to file an agreement to assign oversight to one IRB? ( ) Yes ( ) No
If yes, contact Elaine_Major@uml.edu for assistance.

5. Will any of the collaborating researchers from outside organizations be involved in interventions or interactions with the participants? (X) Yes ( ) No
If yes, do they have a current professional license for the activity? (X) Yes ( ) No
If no, explain:

D. RESEARCH ACTIVITIES

1. Check all that will apply to your participants for this research:

(X) Analyze data previously recorded
( ) Test or record physiological measures
(X) Contact by mail, email, or telephone
(X) Observe or record spontaneous behavior
(X) In person interview
( ) Manipulate participants
(X) Internet survey
( ) Collecting tissues or fluids
( ) Medical Record Review
(X) Questionnaires/survey
( ) Photographs
(X) Audiotapes/Videotapes/Recordings
(X) Incentives
(X) Using control group and study group
( ) Transcription Services (interview, focus group)
( ) Other, explain:

2. Do you intend to recruit from any of the following special populations? (X) Yes ( ) No

If yes, **c**heck the type of participants and be aware that Full IRB Review may be required if greater than minimal risk:

(X) Minors under the age of 18
( ) Pregnant Women
( ) Fetus/Fetal Tissue
( ) Prisoners (Full review required)
( ) Economically/Educationally Disadvantaged
( ) Cognitively Impaired.
( ) Non-English Speaking Participants
( )Other:

3. Categorize the risk of the research:

(X) No more than minimal risk.
( ) Greater than minimal risk.

E. RESEARCH SUMMARY (Complete all sections on this form. Do NOT say 'See Attached'.

1. Describe the research purpose and objectives:

The project is entitled "Middle School Computer Science Pathways." The study is a computer science curriculum development effort at the middle school level with two school districts (Medford and Everett, MA). Computer science activities will be integrated into the schools' existing technology and engineering courses. Additionally, all students who take the school-year courses will be invited to participate in a free one-week summer camp. The project's goal is to: a) assess students' computational thinking as a result of project activities; b) evaluate whether the project achieved desired results; c) evaluate differences in outcomes after controlling for student demographic characteristics.

2. Describe the research methods:

The project will gather data from students (n=1350 over the 3 year span) and teachers (n=11). Student data will include online pre/post surveys and analysis of student work artifacts. From summer camp students (n=360), we will also include analysis structured focus group interviews and performance assessments. The focus group sessions will be about 30 minutes and will be conducted in the main classroom. The performance assessments will take about an hour and will be conducted in the main classroom. Researchers will take notes in realtime, but will not audio record these activities. About 20 students per year will participate in these additional research activities, as a part of camp work. Also, the school districts will provide administrative data on project students, including ethnographic and gender information, which we will match to survey and other data gathered from student work.

From teachers, we will use pre/post surveys for data collection.

All students working on the project will complete IRB training and will keep project data confidential. Students will be added later, after funding is secured. Project data will be destroyed three years after project completion (August 2020).

For the work with students during the school year, the classroom teacher will hand out consent forms (for parental signature) and a student assent form. The teacher will collect these and provide to researchers. During the school year work with students, the research component of the project is three things: a pre-survey, a post-survey, and review of students' work by researchers after the instructional module is complete.

Teachers will be assisting with this work by collecting consent and assent forms. We will have parents and students returned the forms in sealed envelopes, so that teachers will not know which students are participating in the research. The project evaluator and her staff will administer the pre/post survey, and arrange for an alternate, computer-based activity for those students who are not participating in the research.

For review of students' work, teachers will submit all student work to the research team, and researchers will exclude from study the work of students who are not part of the research.

For the summer camps, teachers will assist by handing out informational packets to all students who participated in the school-year educational curriculum. All students will be invited to the camps, whether or not they participated in the school-year research.

The informational packets will include an overview of the camp's activities ("14-114-MAR-XPD summer camp recruitment flyer 6-30-14.doc"), a parent research consent form ("14-114-MAR-XPD icf parent 'summer camp' 7-1-14.docx"), a student research assent form ("14-114-MAR-XPD assent 7-1-14.doc"), and a separate camp application form (to be developed later by each of the two partner school districts). Other school personnel, such as guidance counselors, may also be involved in disseminating the educational opportunity of the camps to students. Teachers and these other personnel will simply hand out the informational packets and receive them being returned. They will not be involved in reviewing the research consent (or lack thereof) of participating students.
For the work with teachers, the project evaluator will provide ICFs to the teachers along with the teacher recruitment materials ("14-114-MAR-XPD CSTeacher Participant Posting 7-1-14.docx"). Teachers will complete a survey as part of their participation (enclosed "14-114-MAR-XPD Teacher_Survey 7-1-14.pdf"). This will be done online. The teacher survey will take about 20 minutes to complete.

Student surveys and other student data will be identified with first initial, last initial, month of birth, and teacher name. This will provide some obscuring of student identity on the research data, but will allow us enough information to match with data provided by the school district. Further procedures for protecting the confidentiality of research participants are described in section G. The student survey will take about 20 minutes to complete ("14-114-MAR-XPD Student_Survey 7-1-2014.pdf").

Please see included commitment letters from the superintendents of the two districts, providing endorsement for this research plan.

3. **Describe the participant population**: The project curriculum will be provided to middle school students in Everett and Medford. At each project school, the curriculum will be offered to all students at one particular adoption middle school grade (e.g., one school may implement the project at 6th grade and another at 7th, but in the given school, all students in that grade will receive the project curriculum).

All students who participate in the project will be asked to participate in the research and evaluation activities; project teachers will assist by having students bring home parental consent forms. Students will receive the same curriculum regardless of whether their parent's consent to use their data for research purposes. A total of 11 teachers over the course of the project will be asked to complete surveys and will receive a stipend for research participation in data-gathering activities.

4. Recruitment Information

a. Describe how you will recruit the participants: STUDENTS: For the school year, no recruitment will be necessary, as project activities will be part of regular instructional activity. For the summer program, teachers will distribute information to all students, inviting all of them to come to a 1-week camp. The attached flyer is how the camp will be advertised ("Computer Science Camp.doc").

We anticipate about 1/3 of the school-year students to participate in the summer camp. TEACHERS: administration will invite teachers to participate in the project (two teachers from each of two middle schools in Medford, and one teacher from each of five middle schools in Everett), plus several additional teachers may volunteer. The attached flyer shows how administration will communicate with teachers ("CSTeacher Participant Posting.docx").

b. Indicate the anticipated number of participants: 1350 students and 11 teachers.

c. Are enough participants being recruited to achieve the objectives of the research (e.g., to provide for statistical analysis or to achieve saturation of a topic)? yes

Explain: Presuming that the population of middle school students in each district over the three years of the project is 3000, we would need a sample of 278 students participate in the research to have a confidence interval of 5% and a confidence level of 95%. We anticipate that there will be large differences in mean scores on the pre and post-surveys given that the students have not participated in computer science curriculum to date. We calculated power with a sample of approximately 1000 students participating in the research over the three years which is sufficiently large to detect small effect sizes (d=.02).

5. Estimate the anticipated Start Date: August 2014
Estimate the anticipated End Date: August 2018

6. Will the research be conducted with Non-UMass Lowell collaborators or collaborating agencies? (X)Yes ( )No

a. If yes, describe how the collaborator will be involved in the research (include details as to whether they are serving as a study site, providing support, or engaged in the research activity by intervening or interacting with the participants): External project evaluator Diane Schilder, Principal Evaluator of EAS, Inc. will administer the student and teacher surveys and manage the student administrative data provided by the districts. Prof. Martin and his research students (to be added to the project after funding is received) will lead the structured interview and performance assessments with project students.

b. Provide letters of support from each collaborator and list the names and addresses of each here:

• Diane Schilder, EdD, Mifflin Place, Suite 400, Cambridge, MA 02138 Phone: (617) 816-2026 (day), (781) 641-0794 (evening); email: DSchilder@eval-inc.com (Diane is senior personnel on the NSF submission – her CV is provided.)

• Roy E. Belson, Superintendent, Medford Public Schools, 489 Winthrop Street, Medford, MA 02155, Phone: (781) 393-2442, rbelson@medford.k12.ma.us

• Frederick F. Foresteire, Superintendent, Everett Public Schools, 12 Vine Street, Everett, MA 02149, (617) 394-2400.

7. Does research involve the use of publicly available or currently existing data?
(X) Yes ( ) No

a. If yes, list source of the data or specimens: Medford and Everett Public Schools will share currently existing school administrative data—student gender and ethnographic information. All data files will be stripped of identifying information.

b. Indicate whether the data is currently de-identified or how it will be de-identified: The districts will de-identify all data and will create unique identifiers for each students.

8. Will you be providing any incentives to the participants? (X)Yes ( ) No

a. If yes, check the type: (X) Cash ( ) Gift Card

( ) Academic Credit ( ) Lottery Chance
( ) Other, list:

b. Specify the amount provided:

Students will not receive any incentive for participation.

Teachers will receive $40 per hour for professional development (PD), and $500 for assisting in classroom data collection. In the first project year, teachers will receive 38 hours of PD, for a stipend of $1,520. In the second and third project years, teachers will receive 46 hours of PD, for a stipend of $1,840.

c. Provide justification for why the incentive is necessary: Teachers are compensated at a fair rate for their personal time made available to participate in professional development to learn new curriculum material. Also, they will be completing data collection protocols and making time available to the research and evaluation teams to conduct observations, focus group, and interviews. This latter incentive is designed to compensate teachers for this additional time.

d. Indicate how you will handle payment if the participant withdraws part way through the study: All teachers will be informed that if they participate in the study, they will be given the incentive. If teachers leave their positions prior to the end of the academic year, we will provide the data-collection stipend if this work is complete. Teachers will receive pay as the work is conducted, approximately monthly, so if they leave the project mid-year, they will receive compensation for the work already completed.

9. Check all of the supporting materials submitted with this application:

(X) Questionnaires, Surveys
(X) Standard Research Tools
( ) Recruitment Materials
(X) Consent Forms
( ) Photo/Video Release Form
( ) Other, list:
( ) Screening Criteria
(X) Letters of Support
(X) Training Certificates
(X) Assent Forms
( ) Confidentiality Agreement for Transcription Services

10. Check all of the materials that will be submitted at a later date:

(X) Translated Document
(X) Final Survey/Interview Tools
(X) Recruitment Materials
( ) Other, list:
(X) Certification of Translation
( ) Letters of Support
( ) Collaborative Agreement

F. INFORMATION FOR RESEARCH WITH SPECIAL POPULATIONS (Check all that apply)

(X) For research with participants under the age of 18, complete F.1.
(X) For research with participants with English as a SECOND language, complete F.2.
( ) For research with all other protected categories, complete F.3.
( ) If no special categories apply to your research, skip to section G.

1. Participants under 18 years of age.

a. Informed consent will be obtained from at least one parent or guardian.
(X)Yes ( ) No

b. Describe the process for how parental informed consent will be obtained: Project teachers will have students bring the parental consent letter home.

c. Will you also obtain assent from the participants? (X)Yes ( ) No

If yes, describe the process to obtain assent from the participants: In the summer camps, we'll ask students if they wish to participate in the additional research activities (performance assessment and structured interviews)

d. Justify why you must use this group of participants for the research: The core project is to develop and test curriculum to teach computer science to middle school students, so we need to work with this age group.

2. Participants with English as a Second Language:

a. List the languages that materials will be translated to:

Both Everett and Medford perform a home language survey with all families. Everett has as many as 15 languages spoken at home across the district. Both districts translate documents on an as-needed basis. For this project, we will determine the home languages of project student participants at the beginning of the school year, when students are assigned to teachers and teachers have determined which at grade level the project curriculum will be offered. Once this information is known, we will translate and back-translate the parent informed consent forms (school year and summer versions) into these languages. We will also prepare translations and back-translations of the summer camp promotional flyers, which will be distributed to families in the spring of each year. (The summer camp flyer has not been prepared yet; the first camp offering will be in summer 2015.)

b. List the titles of all materials that will be translated (Do not translate materials until you have approval for the English version.): (1) MS Pathways Parent Informed Consent Letter for In-School.doc; (2) MS Pathways Parent Informed Consent Letter for Summer Camp.doc; (3) summer camp promotional flyer (to be created in early 2015).

c. I will submit an IRB Amendment Form with the translated and back translated materials in addition to a Translation Certification Form for each language.
(X)Yes ( ) No

3. Other Protected Categories of Participants

a. Are any participants members of other protected populations? ( )Yes ( ) No

d. Describe the protected population category:

e. Justify why you must use this group of participants for the research:

f. Describe how this group of participants will be protected to meet all regulatory requirements:

g. Additional information:

G. PRIVACY AND CONFIDENTIALITY INFORMATION

1. Will you be collecting any information that identifies the participants? (X) Yes ( ) No

2. If yes, indicate the type of identifying information to be collected:

STUDENTS: When initially filled out, student surveys will have a student's first and last initials, month of birth, and classroom teacher's name. Students' classroom work may include personally identifiable

information. For researchers' notes during focus group and performance assessment meetings with students, no personally identifiable information will be recorded.

TEACHERS: The number of teachers involved is too small for open-ended survey answers to be truly anonymous. Thus, the written survey will include teacher name so that teachers realize they are disclosing their answers to project personnel. The project evaluator will the only project staff member to directly review teachers' survey answers. She will provide summary information to the rest of the team.

3. Describe how this information will be protected and kept confidential:
STUDENT DATA:
Survey data will gathered using SurveyMonkey. The project evaluator maintains a "gold" level account, which includes encrypted SSL data transfer when survey results are downloaded to the evaluator's computer.

After survey data are downloaded, the following measures will be taken to remove personally-identifiable data from the survey results: (1) a separate key file will be created that maps between student-identifying information (initials, birth month, and teacher name) and an arbitrary, unique identifier; (2) this key file will be kept in an obscure location on the evaluator's computer (not in the same directory as the research data); (3) the survey results on the evaluator's computer will be re-coded with the identifier, and the personally-identifiable data will be removed; (5) the initial survey data on the evaluator's computer with the personally-identifiable information will be removed using a "data shredding" program; and (6) the original survey data on SurveyMonkey will be deleted.

The evaluator will share the key file with the PI, who will use the same key to re-code student project work (taking similar measures to delete original files with identifiable data). The PI will also use the student keys when annotating focus group and performance assessment records.

The key file will also be provided to the districts, which will re-code student data using the keys before providing it to us.

TEACHER DATA:
The only data that will be gathered from teachers will be via surveys. The evaluator will be handle these files in a similar manner to those of the student data, including the creation of a separate key file and re-coding the survey responses with the key.

4. Describe where the information will be stored: Data will be stored in password-protected files on password protected computers. Computers will be located in the evaluator's office and the faculty researcher's office.

H. RISK INFORMATION

1. What is your assessment of the level of risk? Federal guidelines state that risk "is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (Greater than minimal risk requires Full Review)

(X) No more than minimal risk.

( ) Minor increase (i.e., no significant threat to the person's health or well-being) over minimal risk.

( ) Greater than minimal risk
- ( ) **a.** Potential for direct benefit to participant.
- ( ) **b.** No potential for direct benefit to participants.

2. Describe all potential risks to participants in the research and why you believe it to be of minimal risk:. STUDENTS: There is some risk of students' performance data, including survey answers, classroom work, focus group comments, performance assessment notes, and/or district data being inadvertently exposed. If made public, this could be harmful to the social relationships of the students.

TEACHERS: There is some risk that teachers' survey responses will indicate that their technical competence is below that of their peers. The project evaluator will be the only one to handle these data, and she will use the described security measures to mitigate harm in case survey results were exposed. From the standpoint of their larger role in the school community, it is conceivable that they might feel pressure to participate in the project (since it is an initiative supported by school administration).

a. If risk may appear be greater than minimal but you believe it should be considered within minimal risk parameters for this population, please explain:

3. Indicate how you will minimize risks outlined above to participants: For both students and teachers, the security measures described in Section G will be used to mitigate risks of inadvertent data exposure. For teachers only, the recruiting documents that will be used to invite teachers to participate in the project are included in this application. It will be an application process. Only teachers who wish to participate will apply.

4. Are there alternative methods to acquire the information that could avoid the risks?
( )Yes (X)No
If yes, explain:

5. Do you plan to record or test physical responses as part of the research?
( )Yes (X)No

If yes, I, and my co-investigators, understand how to activate the emergency response procedure for the university or site at which the study will be conducted.
( ) Yes ( )No

I. BENEFITS INFORMATION (Compensation is not a benefit.)

1. Describe the direct or potential benefit of this research to the participants involved: There are likely no direct benefits to participants from being involved in the research however participating students will receive access to enhanced educational instruction and summer camp that focuses on computer science. The research and study teams hypothesize that the participants will benefit from the enhanced educational opportunities by increasing content knowledge, improving attitudes toward computer science, and ultimately by pursuing coursework that will lead to increased employment opportunities.

2. Explain the risk vs. benefit and how the risk is justified by the benefit for the participants in this study. (If using both a study group and a control group, more than one level of risk may be involved.): The benefits of increased content knowledge and exposure to computer science outweigh the risks. Students who serve in the comparison group will be receiving the same curriculum they would otherwise receive even if the research and evaluation were not taking place.

3. Describe the potential benefits of the research to society as a whole. Include only those benefits that may result from the research (as distinguished from benefits of therapies participants would receive even if not participating in the research): The project will disseminate research and evaluation findings to assure that lessons learned from the project can inform other states and district's policies regarding computer science to increase computer science knowledge and the likelihood that students will enter the computer science field.

4. Indicate what, if any, benefits may accrue to individuals who are not participants, but who are similar to the participants in terms of social characteristics (e.g. those who are the same socioeconomic status, gender, race/ethnicity, age, immigration status, disability status or medical status): Students who are not participating in the research and evaluation activities could, nevertheless, benefit from the findings of the research if other states and districts implement policies to support their increased knowledge of computer science and exposure to experiences that could improve their attitudes toward computer science. Also, we expect that the two partner districts will adopt the curriculum that is developed after the research project concludes.

J. INFORMED CONSENT INFORMATION

1. Are you submitting an informed consent document? (X) Yes ( )No

a. List the title of each consent form submitted (ex. 'Focus Group Consent', 'Interview Consent): Three documents: (1) MS Pathways Parent Informed Consent Letter for In-School.doc; (2) MS Pathways Parent Informed Consent Letter for Summer Camp.doc; (3) MS Pathways Teacher Informed Consent Form.docx

b. Check one:
( ) Consent will be done in a group setting
(X) Consent will be done individually
( ) Consent will be embedded in a survey document or questionnaire.

c. Describe who will be obtaining consent for this study: Project teachers will send home parent consent letters. The project evaluator will obtain consent from project teachers.

d. Where will this process and discussion take place: The parent informed consent letter will be sent home to parents at the beginning of the academic year as part of a package of materials that include student handbook and school forms. The teacher form will be presented when teachers are recruited.

e. Will any audio recordings, video recordings, or photographs be used?
(X)Yes ()No
Note: Make sure the Informed Consent document includes which of these will be used and the date the material(s) will be destroyed or erased (not to exceed three years from the completion of the research).

If yes, complete the following:

i. Describe the purpose for collecting these materials: The exact words used by students to describe their work process, and a log of their activities during the performance assessments, will be instrumental in understanding their learning. Thus, we request approval to audio-record these sessions.

ii. Indicate the date the materials will be destroyed: August 1, 2020.

iii. Will any of these materials be used for publication? ( )Yes (X) No
If yes, also submit an IRB Video/Photo Release Form for approval.

2. Are you applying for any type of Waiver of the Informed Consent Requirement?
( )Yes (X) No If yes, complete the rest of this section.

a. ( )Request to Waive Consent Entirely or Allow Alteration for Consent.
Explain why this research involves no more than minimal risk to the participants or their privacy:

i. Explain why the waiver will not adversely affect the rights and welfare of the participants:

ii. Explain why the research could not be carried out without the waiver or alteration:

iii. Explain how the participants will be provided with additional pertinent information after participation (For example, in deception studies).

b. ( )Request to Waive Documentation of Consent (The consent process will be completed with an IRB approved form, but no signed forms will be collected.) Check the option below and justify the waiver request that best meets the purpose of the request.

( )The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality or discovery that they had participated in such research. Each participant will be offered a copy of the informed consent form but may refuse it. Explain:

OR

( )The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Explain:

K. PRINCIPAL INVESTIGATOR ASSURANCE AND SIGNATURE PAGE

Check each box to verify you understand and agree to the following:

(X) I agree to follow the UML IRB Policies and Procedures.

(X) I agree to conduct the study(s) in accordance with the approved protocol and will not modify or revise a protocol until an IRB Amendment Form is submitted and approval is received from the IRB and/or sponsor, except when necessary to protect the safety, rights, or welfare of participants.

(X) I agree to personally conduct or supervise the described investigation(s).

(X) I agree to inform all research participants of the investigational nature of this project as required in 21CFR56 and 45CFR46.

(X) I will ensure that the requirements for obtaining informed consent are met per the regulations found at 21CFR56 and 45 and 45CFR46.

(X) I agree to immediately report to the Office of Institutional Compliance(OIC) any unanticipated events or adverse experiences that occur during the course of this research. OIC will assist in notifying the sponsor, FDA, OHRP or any other agencies as required.

(X) I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(s) are informed about their obligations to follow UML IRB Policies and Procedures and all confidentiality requirements.

(X) I agree to maintain adequate and accurate records, including copies of all consent documents, and to make those records available for inspection in accordance with the regulations. (Records must be kept on file 3 years from the project completion date.)

(X) I understand that UMass Lowell students must be recruited by public announcement and not by personal solicitation.

(X) I understand I must submit an IRB Annual/Continuing Review Form at a minimum of once per year, and an IRB Final Report Form at the conclusion of the study.

( ) I understand that any medical procedures or treatments of human participants will be performed by or under the supervision of a person who is licensed or certified to perform that particular procedure.
(X)Check here if N/A.

(X) I understand all investigators associated with this research must renew their human participant research training every 3 years.

(X) I understand that the research may not begin until I have received the official notice of approval from the IRB.

Project Title: Middle School Pathways in Computer Science

The signature page only may be submitted as a scanned document, faxed to x6012, or sent by intercampus mail to the IRB Administrator at *Wannalancit, 2nd Floor. The entire application should be emailed as a word document to IRB@uml.edu*

SIGNATURE: NOTE: *Students are not eligible to sign this page.*

PI Signature:	Date: July 1, 2014
Printed Name: FRED G. MARTIN	