IRB EXEMPT STATUS APPLICATION

IRB No.: 16-061-MAR-EXM Rev. No./Date: 2/4-11-16

Submit all documents to IRB@uml.edu Date Submitted to IRB: 3/29/16

(This form is ONLY for minimal risk research where no identifiers are collected.)

A. GENERAL INFORMATION

Project Title: WebSlicer Usability Testing	
PI: Fred Martin	Email:fredm@cs.uml.edu
Department: Computer Science	Work Address (Bldg and No.): Olsen Hall 306
Phone: 978-934-1964	Emergency Phone: 978-934-2705
Co-PI(s):	Co-PI(s) Contact Info:
Student Researcher: Michael Meding	Student Researcher Contact info: 214-334-1905

1. Sponsor Information- Check One (Double left click on each check box to access tool.)

(x) Not funded.
( ) Internal funding. Type:
( ) Government/Federal funding. List agency name:
( ) Subcontract. List organization name and include contact name, telephone no., and address:
( ) Other. List organization/company name and include contact name, telephone no., and address:

The proposal to the funding source noted has also been submitted to the IRB: ( )Yes ( )No

2. Project Personnel: Include the PI and all personnel who may interact with subjects or access identifiable human subject data. Training certification should be submitted 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: 06/27/2014 ( ) NIH, Date:
Michael Meding ( )Faculty ( )Staff (x)Student	mike@mikemeding.com	(x) CITI Basic, Date: 03/01/2016 ( ) NIH, Date:
( )Faculty ( )Staff ( )Student		( ) CITI Basic, Date: ( ) NIH, Date:
( )Faculty ( )Staff ( )Student		( ) CITI Basic, Date: ( ) NIH, Date:
( )Faculty ( )Staff ( )Student		( ) CITI Basic, Date: ( ) NIH, Date:
( )Faculty ( )Staff ( )Student		( ) CITI Basic, Date: ( ) NIH, Date:

41e16d377dc500ffbda8e27ba2e36b55

( )Faculty ( )Staff ( )Student		( ) CITI Basic, Date: ( ) NIH, Date:

Additional personnel or other information:

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

B. SCREENING QUESTIONS

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

b. Do other faculty or staff involved with this research have a financial interest in this research activity?
( )Yes (x) No
If **yes**, indicate the nature of the relationship and the conflict(s):

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. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life?
( )Yes (x)No

3. Could disclosure of participants' responses outside the research reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation? ( ) Yes (x)No

4. Does any part of the research require deception or incomplete disclosure of information to participants?
( )Yes (x)No

5. Will prisoners (or their data and/or specimens) be participants in the research? ( )Yes (x)No

6. For research proposed under categories 1-5, is the research subject to FDA regulations? ( )Yes (x5)No

Note: a **YES** for **questions 2-6** above indicates your research does NOT meet exempt criteria. Submit an Application for Expedited or Full Review.

C. EXEMPT CATEGORY CLAIMED (check all that apply):

( ) 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research

on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

If you checked this category, to do the research under this exempt category, it must be conducted in commonly accepted educational settings and not deviate from normal educational practices.
Is this true? ( )Yes ( )No If no, please submit an application for expedited or full review.

(X) 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, **unless**: Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

If you checked this category, the activity may **not** involve any interactions of the researcher with children, if they are participants. Does it involve interactions with children? ( )Yes (X)No
If yes, submit an application for expedited or full review.

( ) 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: the human subjects are elected or appointed public officials, or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

( ) **4.** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

For research under this category, will any of the data, documents, records, or biological specimens be collected or created **after** the date of this application? ( )Yes ( )No
If yes, submit an application for expedited or full review.

For research under this category, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that subjects could be identified directly or through identifiers linked to the subjects? ( )Yes ( )No
If yes, submit an application for expedited or full review.

( ) **5**. Research and demonstration projects conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

( ) **6**. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

D. **RESEARCH ACTIVITIES-Check all that apply:**

( ) Internet or email data collection
( ) Existing data, publicly available
( ) Existing data, NOT publicly available
( ) Focus groups
( ) Audio recordings
( ) Other:

(x) Observation of participants
( ) Record review
( ) Research using existing specimens
(x) Surveys or questionnaires
( ) Interviews

41e16d377dc500ffbda8e27ba2e36b55

E. **RESEARCH SUMMARY**

1. Describe the research purpose and objectives: In this research study, we are evaluating a web-based 3D print slicer. Participants will choose a small model or figure from a set of pre selected models and follow the steps provided in the “Task Instructions” document to take that model from design to printable file. The objective of this study is to gain insight into the usability of this software so that it may be evaluated and improved as part of the thesis study.

2. Describe the research methods: Participants will be recruited via email. Upon response from recruitment email participants will choose a time to join us in our lab Olsen 306, From there, participants will be asked to review the consent form (which will be provided as a web link) and then indicate that they have read the form and consent to the study in an online survey form. If they indicate they have not read the consent form, or decline consent, the session will end there. Sessons will last between 20 to 30 minutes depending on the amount of prior knowledge that the participant has of 3D printing and its surrounding technologies. Prior knowledge is not required to participate in this study. Upon consent, participants will be asked to complete a pre-activity survey on a computer in our lab Olsen 306. Then participants will be provided a printed version of the Task Instructions, and asked to use the web-based software to perform the set of tasks described therein. While each participant is completing the tasks, the researcher will record brief observations on a observations form (attached). After the tasks are complete, participants will be asked to take at post-study survey (which is provided as a continuation of the pre-survey). During this time, they can watch the 3D printer output a model. At the conclusion of the study, participants will receive a previously-printed model as a token of appreciation for their participation. The researcher will match surveys and observation notes by numbering the first participant “1”, the second “2”, and so on, on the observation form. No personally identifiable data will be collected during this study.

3. Describe the participant population: Students and faculty at UMass Lowell whom have little to no knowledge of 3D printing or its surrounding technologies.

4. Recruitment Information

a. Describe how the participants will be recruited:
Students will be recruited via email from the Computer Science email message board. The recruitment email will be sent from the PI’s email and responses will be sent to the student researcher’s email as included in the instructions in the email.

b. Indicate the anticipated number of participants: 6 to 8

c. Will any participants be under 18 years of age? ( )Yes (x)No

If yes, justify and describe how you will meet the exemption requirements:

5. Estimate the duration of the study: 1 Month

6. Will all of the research activities be conducted at UMass Lowell? (x)Yes ( )No

a. If no, list the site/collaborator(s):

b. A letter(s) has been submitted to the IRB from the collaborator to document how they intend to support the research. ( ) Yes ( )No

7. Describe how participants will provide consent: Participants will be asked to read a consent form and then asked to click yes or no on the survey page.

41e16d377dc500ffbda8e27ba2e36b55

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

a. If yes, list source of the data or specimens:

b. Indicate whether the data is currently de-identified or how it will be de-identified:

9. Describe any potential risk to participants from participating in the research: There is no more than minimal risk to participants since no identifying information will be collected. Participants who experience discomfort from using a computer will be advised in the consent form to refrain from particpating.

10. Indicate how you intend to minimize any risks to participants: Participants will be informed that they may leave the study at any time should they feel uncomfortable and no identifying information will be collected.

11. Describe procedures to protect participants' privacy and confidentiality: Personally identifiable data will not be collected.

12. Describe the potential benefits from the research: Design improvements of the software being researched.

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

(x) Questionnaires, surveys

( ) Standard Research Tools (published testing materials, etc.)

(x) Recruitment Materials

(x) Consent Documents

(x) Other, list: Observation rubric to be used by researcher while participant completes tasks; Task Instructions document.

F. PRINCIPAL INVESTIGATOR ASSURANCE AND SIGNATURE

(X) I understand that, as the PI, I am ultimately responsibility for the protection of the rights and welfare of human participants and the ethical conduct of research under this protocol. I agree to conduct the study in accordance with the approved protocol and ensure that all personnel involved in the research will do the same.

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

(X) I certify that the information provided in this application is complete and correct, and believe that my project qualifies as Exempt from the Federal Regulations.

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

(X) I agree to maintain copies of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human participants for three years following termination of the project,

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

(X) I understand it is my responsibility to resubmit an application to the IRB if I need to make any changes that alter the exempt status determination and approval.

41e16d377dc500ffbda8e27ba2e36b55

(X) I understand this project will be closed by the IRB one year from the date of approval and records will be retained in the IRB office for 3 years after that date.

Project Title: WebSlicer Usability Testing

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: /s/ Fred G. Martin	Date:3/29/16
Printed Name of PI: Fred G. Martin	

OR (X) Check here if submitted electronically from the PI's email account.

41e16d377dc500ffbda8e27ba2e36b55