eNable Prosthetics

A Guide to 3D Printing Prosthetics for People Using and Modifying designs from the eNable Foundation

A Node of the MakerWeb Consortium

Managed by Amanda Ervin
Makerspace Coordinator

&

Diego Bazan ‘18

Table of Contents

UNION COLLEGE HUMAN SUBJECTS REVIEW COMMITTEE

2016-2017 APPLICATION TO ENGAGE IN RESEARCH INVOLVING HUMAN SUBJECTS

Please type your responses in the fields provided. The grey fields will expand if more space is needed. When completed, please print and deliver to Joshua Hart, Chair of the Human Subjects Review Committee, Bailey Hall 302. Emailed, hand-printed, or unsigned applications will be returned unreviewed. Blue links can be followed by holding the "control" key and clicking.

1. Name of student researcher (if applicable) > Diego Bazan

   Box number >
   Email address >

   Major > Computer Engineering

2. Name of faculty researcher or sponsor > Amanda Ervin

   Office location >

   Email address >

   Department > MakerWeb ITS

3. Title of project > eNable 3D Printed Prosthetics

4. Is this research funded? > yes

   If yes, by whom? > MakerWeb

continued...

5. Approximate number of participants: > 5 per year max

Approximate age range of participants: > any age

Other important characteristics of participants (e.g., prisoners, minors, participants in poor mental or physical health, etc.) > people with severed or disabled limbs

6. Where will the data be collected? > Schenectady NY, Israel, Palestine

7. If data will be collected at a location other than Union College's campus, identify how you secured permission from the appropriate individuals at the other location(s). Include this individual's name and contact information. > We are working with Physicians for Human Rights Israel. If this goes forward, she will work with patients in Israel and Palestine to take accurate measurements and send them to us. We will also ask her for any international accommodations necessary for this IRB. Her contact info is: (omitted for privacy)

8. How will participants be sampled, recruited, or otherwise enlisted? > we have a connection with Physicians for Human Rights, but we are also listed on the eNable Foundation's website. We expect most of our participants to contact us through that listing.

9. What rewards, payment, or other credit will be provided for participation, if any? > Participants will receive a 3D printed prosthetic, the cost of this prosthetic will be covered by the MakerWeb Consortium

10. How will the anonymity of participants and/or the confidentiality of the data be ensured? > I have designated 3 options for confidentiality. Participants are asked to list themselves as either anonymous, confidential, or "free to share". In anonymous cases, we will log information for design purposes, once the design is complete, the information will be destroyed. In confidential cases, we will retain the information to be used in logging statistics, and possibly in research papers, but any names, references, or identifying links to the individual will be untraceable. In "free to share" cases, participants are allowing us to use their name and information to discuss this work, and to display this information for PR purposes.
continued...

For the following items, indicate YES or NO. If the answer is YES, please explain.

11. Is it reasonably possible that any of the participants will be placed at risk with regard to physical pain or discomfort, psychological stress or discomfort, or social injury (e.g., diminished reputation or damaged social or personal relationships)? > no

12. Will information that might affect participants' willingness to participate be withheld from them prior to securing informed consent to take part in the research? > no

13. Will there be any coercion or penalties that might negate a participant's freedom to refuse to participate in the study or withdraw from participation? > no

14. Will any of the researchers who will be conducting the study be placed at risk with regard to physical or psychological pain, discomfort, or harm? > no

15. Will any deception be involved? If so, explain the nature of the deception, the need for the deception, and how risks from that deception will be mitigated. > no

16. Will topics or questions about depression or about thoughts of or attempts to engage in of self-injury or suicide be included? > no

For the following items, indicate YES or NO. If the answer is NO, please explain.

17. Will all promises and commitments made to the participants regarding their participation be duly honored by the researcher? > yes

18. Will it be made clear from the onset of the study that participants are free to withdraw from the study at any time? > yes

19. Immediately following their participation, will all participants be provided with a complete explanation (debriefing) of the nature of the study so as to eliminate any possible misconceptions about its purpose and to eliminate any stress or discomfort experienced by participants? > n/a

20. If payment is offered, immediately following their participation, will all participants be provided with payment as promised (e.g., credit for course, gift certificate, etc) ? > n/a

21. The United States Government, via 45CFR46.116(d), states that informed consent must be obtained from participants unless, among other criteria, it is not practicable to do so.

If you do plan to obtain informed consent, please indicate how, whether it be an informed-consent form, a clickable button on a Website, or via other documentable means: > paper form

If you do not plan to obtain informed consent, please explain how your study meets each of the four criteria for waiving this requirement as set forth by 45CFR46.116(d). *You cannot simply state that you don't think informed consent is important or that the study is brief or anonymous. You must explain how your study qualifies for a waiver according to 45CFR46.116(d).* >

22 (*OPTIONAL*). In addition to the specific explanations that may have been provided with the responses to items #11 through #21, you are welcome to provide any further comments that might help the Committee determine whether the proposed research is likely to produce benefits so significant as to outweigh any questionable or risk-producing research procedures. >

PLEASE ATTACH THE FOLLOWING APPENDICES.

APPENDIX A: Briefly explain the purpose of the research and provide a general description of the methods to be employed (200 words should be sufficient).

APPENDIX B: Provide a copy of the informed consent materials you plan to administer to participants (unless you have made a case for not using one in #21. Whether you use the sample form found here or the OHRP checklist found here, please ensure that your form contains all the elements called for by OHRP.

APPENDIX C: Provide a copy of all materials to be used in your study. If an interview procedure is to be used, a detailed list of the types of questions that will be asked should be described. If participants will be exposed to any stimuli, copies of those stimuli should be presented. In the case of oral presentations, a transcript is sufficient. To be clear: anything a participant will read, see, be asked, or answer needs to be included here.

APPENDIX D: Provide a copy of the debriefing to be presented to participants, either in text or orally. A debriefing statement is a statement presented to participants after their participation. It should provide some information about the research study in which they just participated. It need not provide detailed discussions to include literature reviews or full hypotheses, but it should provide the participants with at least a basic understanding of what the research is about. If it is not feasible to provide a debriefing, please explain why.

continued...

CERTIFICATION: I/we certify that:

The statements herein are factual to the best of my/our knowledge;
I/we have described our methods and materials accurately and completely;
I/we have not begun data collection in any way and will not do so until given HSRC approval;

If the proposal is approved, I/we will not make any modifications to the study until receiving additional HSRC approval;
I/we understand that the approval, if granted, expires one year from the initial approval date.

Diego Bazan	3/30/2017
Student researcher (if applicable)	date
Amanda Ervin	3/30/2017
Faculty researcher/advisor	date

Appendix A

Description of the eNable Project

eNable is a nationwide foundation dedicated to bridging the gap between those who have 3D printing means, and those who want 3D printed prosthetics. eNable provides 3D models and 3D printing instructions to Makers with 3D printers, and helps connect those Makers to people in the community who want 3D printed prosthetics. Recipients of these prosthetics are primarily kids.

One goal of this work, is to consider that 3D printing prosthetics is much less expensive than traditional means of acquiring prosthetics. Kids grow so fast that it's not usually economically viable to manufacture prosthetics for kids who will outgrow them in a year or two.

As a member of the MakerCorps, Diego Bazan is heading up a co-curricular project, with support from Amanda Ervin, Makerspace Coordinator, the MakerWeb Consortium, and the eNable Foundation. The Union College Chapter of the eNable Foundation will operate under the umbrella of the MakerWeb Consortium. Together, we will provide 3D printed prosthetics for kids and adults who need them. Measurements will be taken of participants' limbs and 3D models will be created to fit those limbs. Prospective participants include kids from the Schenectady community, and a group called Physicians for Human Rights Israel. Dana Moss, from the group Physicians for Human Rights Israel, contacted Professor Rieffel looking for prosthetics, and he connected her to the MakerWeb Consortium.

eNable provides pre-designed 3D models suited for these purposes. The MakerWeb will make modifications to the designs, and 3D print them themselves. Any modifications made to these 3D models will be released back to the eNable Foundation under the same licensing originally granted. This may include designing measurement kits to send to participants in Israel and Gaza. Some questions may be posed to recipients to help understand the effects of the new prosthetics on their quality of life. We may also use feedback from participants to improve initial designs of prosthetics. Diego is soliciting funding as a student group, until that happens, Amanda will provide funding for prosthetics on a case by case basis, and the 3D prints will be made in the Collaborative Design Studio node of the MakerWeb. The total cost for one of these prosthetics will be about $60. We'd also like to host a panel discussion with doctors who specialize in this field, and Makers who make 3D prosthetics, to compare and contrast the different mode of production and viability. We will apply for a Mellon Our Shared Humanities Grant to cover the costs of this panel discussion.

Appendix B

Step by Step Data Collection

In Person Participants

This project focuses on arm limbs, both left and right hands.
Participants will be asked which joints work, and where the limb has been severed or become dysfunctional. This assessment is necessary to determine which type of limb design the participant needs.
Once the type of limb is determined, measurements may include any of the following
1) wrist, forearm, and upper arm diameter
2) hand width
3) finger dimensions
4) length of forearm, upper arm, or hand
5) range of motion of each limb segment

These measurements will be acquired using measuring tape or 3D scans.
In some cases 3D scans may be used to create best fitting 3D models.

Participants who can't come to Union College will be asked to provide the following information:

The eNable Foundation outlines guidelines for taking measurements of a participant's limb, the one a prosthetic is to be made for, in a very simple and easy to understand how-to video. The instructions for measuring participants are as follows:

1) Use the best digital camera you have access to, on the highest resolution possible
2) Shoot pictures outdoors during a bright time of day if possible, otherwise, pictures can be taken in the most well lit place you have access to
3) Hang a ruler, with easy to read markings, from a wall with the center of the ruler being at the height of the recipients nose.
4) Shoot pictures from 6 feet away with the camera at the height of the recipient's wrist.
5) Picture 1, recipient kneels facing a wall, hands and arms are extended vertically and laid flat against the wall, the ruler and arms of the recipient must be parallel with the sides of the picture, take several pictures.
6) Picture 2, the recipient stands and holds the limb for which they would like a prosthetic made for horizontally against the wall facing the camera, the wrist should be flat and level and pressing against the ruler, take several pictures.

7) Picture 3, the recipient stands and holds the limb for which they would like a prosthetic made for horizontally against the wall facing the camera, the wrist should be flexed downwards as far as possible, take several pictures.
8) Picture 4, the recipient stands and holds the limb for which they would like a prosthetic made for horizontally against the wall facing the camera, the wrist should be extended upwards as far as possible take several pictures.
9) Send pictures to Amanda and Diego electronically.

Appendix C

eNable Participant Questionnaire

This work is non invasive and assumed risks are minimal, but please be aware that possible risks associated include skin irritation and pinching or scratching of skin from plastic parts. We also plan to keep a log of the measurement data, and stories about limbs we create. Participants have the ability to choose how much information we retain, and can opt out of the study at any time.

Name of participant: _____

Age of participant: _____

Contact information:

_____
Street Address

_____
City/State/Country

_____
Phone

_____
Email

How would you prefer assistance measuring (select all that apply)?
□ email instructions
□ verbal instructions
□ measurement kit
□ 3D Scan of limb

Recording data about your limb is necessary to complete a design. Consent of participant:
□ Yes
□ No

Continued…

Participants have the option to choose how their information is handled, please see attached form for consent types (Informed Consent Form; Addendum A). This section should be completed by parents if participant is under 18. Please choose only one option.
□ Anonymous
□ Confidential
□ Free to Share

Type of limb difference (select one):
□ Above Elbow
□ Not Enough Wrist for a Wrist
□ Functional Elbow but little to no forearm
□ Functional Wrist
□ Not Enough Wrist

List any known material allergies (specific to skin contact - for example; metal, adhesive, foam):

Union College would like to share this work on our website, and other public facing work. We may also include some of the data in research papers.
Consent to photograph (select one):
□ Yes
□ No

Consent to use data (check all that apply):
□ name
□ measurements
□ type of limitation
□ age
□ photographs
□ personal story
□ functional feedback

Request for additional modifications (aesthetic to function changes):

Continued…

Signature of Participant/ Date

Signature of Parent/ Guardian/ Date

If you have any questions, please contact Union College MakerWeb Consortium.

Appendix D

INFORMED CONSENT FORM (participant)

Our names are Amanda Ervin and Diego Bazan, and we are staff and student members at Union College in Schenectady, NY. Amanda manages the MakerWeb Consortium and Diego works for her. We are inviting you to participate in a research study. Involvement in the study is voluntary, so you may choose to participate or not. A description of the study is written below.

We are interested in learning about and creating 3D prosthetics limbs. You will be asked to hold out your arm, so we can scan it with a laser scanner. Measurements will be taken of the limb to be assessed, and we will ask you questions regarding the overall fit and happiness associated with the prosthetic limb we create. This will take approximately 1 hour of questions and 1 hour of measurement time. Additional time may be required at a later date for specialized designs or modifications to the prosthetic. The risks to you when participating in this study are minimal, but do include possible skin irritation, pinching or scratching when trying on the prosthetic. These risks will be minimized by collecting information about skin allergies ahead of time. If you no longer wish to continue, you have the right to withdraw from the study, without penalty, at any time.

Kid language:
Can we scan your arm, in order to make a 3D printed arm? You won't feel the laser scan. The plastic might scratch or rub, but we will do our best to make sure that doesn't happen. We will stop any procedure at any point you ask.

Addendum A:

As we collect the data listed above, you have three consent options; anonymous, confidential, free to share. Choose one of these options from the attached form.

- If anonymous is chosen, data about participants will not be kept beyond the design phase of the project.
- If confidential is chosen, information will be collected, but information about participants will be kept completely private, such that it would be impossible to link your name with any of your responses.
- If participants choose "free to share", their information would be used to highlight success stories, as part of the research being done at Union College.

These stories could be highlighted on our website, http://muse.union.edu/makerweb, and if picked up by any additional news stories, we'd like to have the consent to share this information.

Participants' decision will not affect eligibility to participate in the study, nor to receive a prosthetic limb.

continued...

By signing below, you indicate that you understand the information above, and that you wish to participate in this research study.

Participant Signature Printed Name Date

Appendix E

Parental Consent Form

Our names are Amanda Ervin and Diego Bazan, and we are staff and student members at Union College in Schenectady, NY. Amanda manages the MakerWeb Consortium and Diego works for her. We are inviting your child to participate in a research study. Involvement in the study is voluntary, so your child may choose to participate or not. A description of the study is written below.

We are interested in learning about and creating 3D prosthetics limbs. Your child will be asked to hold out their arm, so we can scan it with a laser scanner. Measurements will be taken of the limb to be assessed, and we will ask your child questions regarding the overall fit and happiness associated with the prosthetic limb we create. This will take approximately 1 hour of questions and 1 hour of measurement time. Additional time may be required at a later date for specialized designs or modifications to the prosthetic. The risks to your child when participating in this study are minimal, but do include possible skin irritation, pinching or scratching when trying on the prosthetic. These risks will be minimized by collecting information about skin allergies ahead of time. If your child no longer wishes to continue, they have the right to withdraw from the study, without penalty, at any time.

Addendum A:

As we collect the data listed above, you have three consent options; anonymous, confidential, free to share. Choose one of these options from the attached form.

- If anonymous is chosen, data about participants will not be kept beyond the design phase of the project.
- If confidential is chosen, information will be collected, but information about participants will be kept completely private, such that it would be impossible to link your name with any of your responses.
- If participants choose “free to share”, their information would be used to highlight success stories, as part of the research being done at Union College.

These stories could be highlighted on our website, http://muse.union.edu/makerweb, and if picked up by any additional news stories, we’d like to have the consent to share this information. **Participants’ decision will not affect eligibility to participate in the study, or to receive a prosthetic limb.**

By signing below, you indicate that you understand the information above, and that you wish to participate in this research study.

Participant Signature	Printed Name	Date

Parent Signature	Printed Name	Date