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| | **Massachusetts Institute of Technology**<br>Committee on the Use of<br>Humans as Experimental Subjects | **Protocol #**<br>(assigned by COUHES) | |

**APPLICATION FOR USE OF HUMANS AS EXPERIMENTAL SUBJECTS (STANDARD FORM)**

*Please answer every question. Positive answers should include details. N/A must be marked where the question does not pertain to your application. Any incomplete application will be rejected and returned for completion. This application **must** include the secondary personnel list form otherwise this application will be returned to you.*

## I. BASIC INFORMATION

**1. Title of Study**

Adapting Physical Tools to Facilitate Learning of Motor Skills

**2. Principal Investigator**

| | |
|---|---|
| Name: Stefanie Mueller | Building and Room #:32-211 |
| Title: Assistant Professor | Email: stefanie.mueller@mit.edu |
| Department: EECS | Phone: 6177155831 |

**3. Funding.** *If the research is funded by an outside sponsor, please enclose one copy of the research proposal with your application. A draft of the research proposal is acceptable.* ***Do not leave this section blank. Check all that apply. If your project is not funded, check No Funding.***

A. Sponsored Project Funding:

☐ Current Proposal Grant/Proposal #_____
Sponsor _____
Title _____

☐ Current Award Grant/Account #_____
Sponsor _____
Title _____

B. Institutional Funding:

☐ Gift ☐ Departmental Resources
☒ Other (explain) PIs startup funds from EECS/CSAIL

C. No Funding
☐ This protocol will not be funded

**4. STATEMENT OF FINANCIAL INTEREST**

Does the principal investigator (including their family) or any study personnel involved in the study have a financial interest in a company or other organization participating in or providing drugs, devices, biological agents, investigational medical devices, or any other tangible material or financial sponsorship for the research?

☐ Yes ☒ No

Does this study contemplate any purchases from or subawards to a company or other organizations not named in the study in which you (including your family) hold a Financial Interest?

☐ Yes ☒ No

If yes was checked for any of the questions above, then attach a **Supplement for Disclosure of Financial Interest** for each individual with an interest. *This supplement, together with detailed guidance on this subject and definitions of the highlighted terms, is available in the COUHES site under Policies & Procedures in the Financial Conflicts of Interest section.*

| **5. Anticipated Dates of Research** | |
|---|---|
| Start Date: February 15, 2018 | Completion Date: February 15, 2019 |

**6. Collaborating Institutions.** *If you are collaborating with another institution(s) then you must obtain approval from that institution's institutional review board, and forward copies of the approval to COUHES.*

N/A

**7. Location of Research.** *If at MIT please indicate where on campus. If you plan to use the facilities of the Clinical Research Center you will need to obtain separate approval from the MIT Catalyst Clinical Research Center.*

MIT CSAIL

## II. STUDY INFORMATION

**1. Purpose of Study.** *Please provide a concise statement of the background, nature and reasons for the proposed study. Use non-technical language that can be understood by non-scientist members of COUHES.*

We are building an end-to-end learning environment that supports users in learning motor skills with physical tools. The key idea is to adapt the physical tool based on the current learning progress of the learner. For instance, when learning basketball, learners start out with a basket at a low height and a large hoop. Using sensors, we measure how good learners are hitting the hoop, i.e. if they perfectly hit the hoop and the ball goes in, if they don't hit the hoop but at least hit the board, or if they don't hit the board at all. If learners increase their skill, we then gradually raise the basket and make the hoop smaller to make the learning task more difficult. To automate the process, we use motors for the movement of the different components. The goal of this study is to understand if principles from adaptive learning systems for learning language and math (as used in online education) can be applied to other areas of skill learning, such as motor skills with physical tools, as well.

**2. Study Protocol.** *For* **biomedical, engineering and related research,** *please provide an outline of the actual experiments to be performed. Where applicable, provide a detailed description of the experimental devices or procedures to be used, detailed information on the exact dosages of drugs or chemicals to be used, total quantity of blood samples to be used, and descriptions of special diets.*

*For applications in the* **social sciences, management and other non-biomedical disciplines** *please provide a detailed description of your proposed study. Where applicable, include copies of any questionnaires or standardized tests you plan to incorporate into your study. If your study involves interviews please submit an outline indicating the types of questions you will include.*
*You should provide sufficient information for effective review by non-scientist members of COUHES. Define all abbreviations and use simple words. Unless justification is provided for additional length, this part of the application must not exceed 5 pages.*
*Attaching sections of a grant application is not an acceptable substitute for a description of your study as requested here.*

We will start the experiment by first explaining the purpose of the experiment and procedure to the subject. We will then randomly assign participants to one of the two conditions: the physical tool with only a fixed beginner and expert version (e.g., a low basket with large hoop and a high basket with small hoop) and our new adaptive training tool that provides gradually more challenging versions. We will instruct participants to practice with the tool setup of their corresponding condition for 30 minutes and then run a performance evaluation task at the end. For instance, participants will be asked to practice hitting the basket for 30 minutes and are then asked to throw the ball exactly 20 times for which we measure their success rate. We will also log all sensor data from the practice session (e.g., using a contact sensor on the board measuring if it was hit, and a switch in the basket which measures if the ball went through) and subsequent adaptations made to the tool. At the end of the study, we will compare the data to draw conclusions about the level of engagement (how many trials did participants execute) and the level of skill the participant achieved. We will also ask participants for their feedback on the overall experience using a questionnaire. The total time of this experiment is expected to be less than 1 hour.

**3. Drugs and Devices.** *If the study involves the administration of an investigational drug that is not approved by the Food and Drug Administration (FDA) for the use outlined in the protocol, then the principal investigator (or sponsor) must obtain an Investigational New Drug (IND) number from the FDA. If the study involves the use of an approved drug in an unapproved way the investigator (or sponsor) must submit an application for an IND number. Please attach a copy of the IND approval (new drug), or application (new use.).*

*If the study involves the use of an investigational medical device and COUHES determines the device poses significant risk to human subjects, the investigator (or sponsor) must obtain an Investigational Device Exemption (IDE) number from the FDA.*

**Will drugs or biological agents requiring an IND be used? YES ☐ NO ☒**
*If yes, please provide details:* N/A
**Will an investigational medical device be used? YES ☐ NO ☒**
*If yes, please provide details:* N/A

**4. Radiation** *If the study uses radiation or radioactive materials it may also have to be approved by the Committee on Radiation Exposure to Human Subjects (COREHS). COUHES will determine if you need COREHS approval.*

**Will radiation or radioactive materials be used? YES ☐ NO ☒**
*If yes, please provide details:* N/A
**Will any type of lasers be used YES ☐ NO ☒**
*If yes, please provide details:* N/A

**5. Diets**

**Will special diets be used? YES ☐ NO ☒**
*If yes, please provide details*N/A

## III. PERSONNEL

**Fill out the personnel list attached to this form.** *If the personnel list is not included, the application will be returned to you.*

## IV. HUMAN SUBJECTS

**1. Subjects** (*that will be consented for this study*)

**A. Maximum number of subjects:** 20

**Adults:**20 **Minors:** 0

**B. Age(s):** 18-65

**C. Inclusion/exclusion criteria**

**i. What are the criteria for inclusion or exclusion?** In all studies, subjects must be over 18, in order to give their own informed consent.

**ii. Are any inclusion or exclusion criteria based on age, gender, or race/ethnic origin?** *If so, please explain and justify.* N/A

**iii. Please explain the inclusion of any vulnerable population (e.g. children, cognitively impaired persons, non-English speakers, MIT students), and why that population is being studied.** No vulnerable populations are being studied.

**2. Subject recruitment** *Identification and recruitment of subjects must be ethically and legally acceptable and free of coercion. Describe below what methods will be used to identify and recruit subjects. Attach any and all recruitment documents associated with the protocol (i.e. flyers, e-mails, advertisements, etc.)*

Subjects will be recruited by electronic and physical advertisements (recruitment advertisements are attached).

**3. Informed consent.** *Documented informed consent must be obtained from all participants in studies that involve human subjects. You must use the templates available on the COUHES website to prepare these forms. Draft informed consent forms must be returned with this application. Under certain* ***very limited*** *circumstances, COUHES may waive the requirement for informed consent. If you are requesting a* ***waiver or alteration of consent****, please attach the Waiver or Alteration of Informed Consent Request form.*

**[Attach informed consent form(s) with this application.]**

**4. Subject compensation.** *Payment must be reasonable in relation to the time and trouble associated with participating in the study. It cannot constitute an undue inducement to participate.*

**Describe all plans to pay subjects in cash or other form of payment (i.e. gift certificate):**
Subjects will be paid for their time, $10/hour prorated.

**Will subjects be reimbursed for travel and expenses?**
No

**5. Potential risks.** *A risk is a potential harm that a reasonable person would consider important in deciding whether to participate in research. Risks can be categorized as physical, psychological, sociological, economic and legal, and include pain, stress, invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible by using e.g., appropriate monitoring, safety devices and withdrawal of a subject if there is evidence of a specific adverse event.*

**What are the risks / discomforts associated with each intervention or procedure in the study?**
Minimal risk to subject. No private or sensitive information is involved.

**What procedures will be in place to prevent / minimize potential risks or discomfort?**

We will use an empty room that allows for enough space to throw the ball (the CSAIL Holodeck).

**6. Potential benefits**

**What potential benefits may subjects receive from participating in the study?**
No significant benefits.

**What potential benefits can society expect from the study?**
The study will help improve learning systems for motorskills.

**7. Data collection, storage, and confidentiality**

**How will data be collected?**
Data will be collected electronically for data analysis.

**Is there audio or videotaping? YES ☐ NO ☒** ***Explain the procedures you plan to follow.***
N/A

**Will data be associated with personal identifiers or will it be coded?**

**Personal identifiers ☐ Coded ☒** ***Explain the procedures you plan to follow.***
Each subject will be assigned a number. The researchers will track data and notes by subject number, not by name or other personal information.

**Where will the data be stored and how will it be secured?**
Electronic data will be stored on a secure fileserver with access control. Only members of the research group will have access to the files.

**What will happen to the data when the study is completed?**
Data will be stored for a minimum of three years, and then destroyed.

**Can data acquired in the study affect a subject's relationship with other individuals (e.g. employee-supervisor, patient — physician, student-teacher, family relationships)?**
No. No personal or private data will be collected.

**8. Deception** *Investigators must not exclude information from a subject that a reasonable person would want to know in deciding whether to participate in a study.*

**Will information about the research purpose and design be withheld from subjects?**
**YES** ☐ **NO** ☒

***If YES, explain and justify.***
N/A

**9. Adverse effects.** *Serious or unexpected adverse reactions or injuries, and/or unanticipated problems involving risks to subjects or others must be reported to COUHES within 48 hours. Other adverse events should be reported within 10 working days.*

**What follow-up efforts will be made to detect any harm to subjects, and how will COUHES be kept informed?**
N/A

**10. Health Insurance Portability and Accountability Act ("HIPAA").** *If your study (i) involves individually identifiable health information and (ii) is sponsored by MIT Medical, an MIT Health Plan or another healthcare provider, then you must complete the questions below because HIPAA likely applies to your study. For more information regarding the applicability of HIPAA to human subjects research, please click here.*

**Do you plan to obtain, use or disclose identifiable health information in connection with your research study?**
**YES** ☐ **NO** ☒
*If YES, then all participants must complete an Authorization for Release of Protected Health Information Form. Please attach a copy of this draft form. You must use the template available on the COUHES website.*

*Alternatively, COUHES may grant a Waiver of Authorization in certain **very limited** circumstances when use of individually identifiable health information would pose only minimal risk to study participants (among other requirements). For additional information regarding whether your study might qualify for a waiver, please click here.*

**Are you requesting a Waiver of Authorization?**
**YES** ☐ **NO** ☒
*If YES, explain your rationale for concluding that: (i) use of participant health information poses no more than minimal risk; (ii) the research could not be conducted without the waiver and (iii) the research could not be conducted without the information. In addition, please explain your plan for (i) ensuring the participant health information is not improperly used or disclosed either within MIT or to any outside third parties and (ii) destroying identifiers at the earliest possible opportunity.*
N/A

**Will the health information you will receive for use in this study be de-identified?**
**YES ☐ NO ☒**

*If YES, you do not need to obtain a signed Authorization for Release of Protected Health Information Form from study participants. Note, however, that if you receive identifiable participant health information that you plan to convert into de-identified information for use by other researchers, then you must obtain a signed Authorization for Release of Protected Health Information Form from each participant before receiving their identifiable health information for use in your study.*
N/A

**Will you be using or disclosing a limited data set?**
**YES ☐ NO ☒**

*If YES, and you will only receive participant health information in limited data set form, then you do not need to obtain a signed Authorization for Release of Protected Health Information Form from study participants. You must complete a formal data use agreement with the party from whom you will receive the limited data set information in order for your application to be approved.*

*If YES, and you will receive identifiable participant health information that you plan to convert into limited data set form for use by other researchers, then you must obtain a signed Authorization for Release of Protected Health Information Form from each participant before receiving their identifiable health information for use in your study. You must complete a formal data use agreement in order for your application to be approved.*

## V. INVESTIGATOR'S ASSURANCE

**I certify the information provided in this application is complete and correct.**

**I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by COUHES**

**I agree to comply with all MIT policies, as well all federal, state and local laws on the protection of human subjects in research, including:**

- **ensuring all study personnel satisfactorily complete human subjects training;**
- **performing the study according to the approved protocol;**
- **implementing no changes in the approved study without COUHES approval;**
- **obtaining informed consent from subjects using only the currently approved consent form;**
- **protecting identifiable health information, to the extent required by law, in accordance with HIPAA requirements; and**
- **promptly reporting significant or untoward adverse effects.**

**Signature of Principal Investigator** _____ **Date** _____

**Print Full Name and Title** _____

**Signature of Department Head** _____ **Date** _____

**Print Full Name and Title** _____

**By signing this form you confirm a scientific review of the proposed research has been conducted, and that the proposed research is of scientific and scholarly validity.**

***The electronic file should be sent as an attachment to an e-mail: couhes@mit.edu. In addition, two single sided hard copies (one with original signatures) should be sent to the COUHES office: Building E25-Room 143B.***

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| | **Massachusetts Institute of Technology**<br>Committee on the Use of<br>Humans as Experimental Subjects | **Protocol #**<br>(assigned by COUHES) | |

## PERSONNEL LIST

*This form must be attached to both standard and exempt form applications.* ***Any application submitted without a completed personnel list will be returned to you.***

*Personnel is defined as anyone who plays a role in research involving human subjects, including direct contact, indirect involvement, analysis of data, blood or tissue samples. This extends to principal investigators, associate investigators, student investigators, study coordinators, visiting scientists, consultants, laboratory technicians and assistants.*

*All study personnel must be listed below. This listing must include contact information, a brief statement of qualifications and their study role.*

*Important note: all study personnel are required to complete Human Subject Training before work begins on the project. Proof of training must be attached for non-affiliates. (Documentation from collaborating institutions may be submitted in lieu of training certificates.)*

### A. MIT AFFILIATES

| *Personnel name, and e-mail address* | *Qualifications: Describe briefly* | *Study role(s):* | *Check if obtaining consent* |
|---|---|---|---|
| **Contact***<br>Name: Stefanie Mueller (primary contact)<br>Email: stefanie.mueller@mit.edu | has passed HST | Research Advisor | ☒ |
| Name: Dishita Turakhia<br>Email: dishita@mit.edu | has passed HST | Technical Associate II | ☒ |
| Name: Lotta-Gili Blumberg<br>Email: blumberg@mit.edu | has passed HST | UROP Student | ☒ |
| Name: Yini Qi<br>Email: qyn@mit.edu | has passed HST | MEng Student | ☒ |
| Name:<br>Email: | | | ☐ |
| Name:<br>Email: | | | ☐ |
| Name:<br>Email: | | | ☐ |

***NOTE:** Please designate a person with whom COUHES should communicate regarding issues or questions about the protocol.

**B. NON-MIT AFFILIATES**

| *Name, affiliation, and e-mail address* | *Qualifications: Describe briefly* | *Study role(s):* | *Check if obtaining consent* | *Check if human subject training has been completed* |
|---|---|---|---|---|
| Name:<br>Email: | | | ☐ | ☐ |
| Name:<br>Email: | | | ☐ | ☐ |
| Name:<br>Email: | | | ☐ | ☐ |
| Name:<br>Email: | | | ☐ | ☐ |
| Name:<br>Email: | | | ☐ | ☐ |

**C. STATEMENT OF FINANCIAL INTEREST**

Does the principal investigator (including their family) or any study personnel involved in the study have a financial interest in a company or other organization participating in or providing drugs, devices, biological agents, investigational medical devices, or any other tangible material or financial sponsorship for the research?

☐ Yes ☒ No

Does this study contemplate any purchases from or subawards to a company or other organizations not named in the study in which you (including your family) hold a Financial Interest?

☐ Yes ☒ No

If yes was checked for any of the questions above, then attach a **Supplement for Disclosure of Financial Interest** for each individual with an interest. *This supplement, together with detailed guidance on this subject and definitions of the highlighted terms, is available in the COUHES site under Policies & Procedures in the Financial Conflicts of Interest section.*