Application for Ethical Review of Research Involving Human Participants

Project Info.

File No: 101600
Project Title: Wearables for Type 1 Diabetes
Principal Investigator: Dr. Sowmya Somanath (Faculty of Design)
Start Date: 2019/07/29
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Keywords: wearable technology, HCI, diabetes, physical activity, accessibility, inclusive design, industrial design

Project Team Info.

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Common Questions

1. General Information

#	Question	Answer
1.1	On this application, are you the:	faculty supervisor
1.2	For principal investigators and student investigators, please indicate that you have read and fully understand all ethics obligations by checking the box beside each statement. If you are a faculty supervisor, please ensure that this section is checked off on behalf of your student.	I have read the TCPS2(2014) and agree to comply with the policies and procedures outlined therein.|Any additions/changes to research procedures after approval has been granted will be submitted to the REB.| I agree to request a renewal of approval for any project continuing beyond the expected date of completion or for more than one year.|I will submit a final report once the research has been completed.| I take full responsibility for ensuring that all other investigators involved in this research follow the protocol as outlined in this application.
1.3	For faculty supervisors, please indicate that you have read and fully understand the obligations as faculty supervisor listed below by checking the box beside each statement.If you are not a faculty supervisor, please check "N/A".	I agree to provide the proper supervision of this study to ensure that the rights and welfare of all human participants are protected.|I will ensure a request for renewal of a proposal is submitted if the study continues beyond the expected date of completion or for more than one year.| I will ensure that a final report is submitted to the Research Ethics Board via the research portal.|I have read and approved this application and proposal.
1.4	If you are a faculty supervisor, please state which student activity this research is for. If you are not a faculty supervisor, please select 'not applicable'.	graduate MRP
1.5	If this is a course assignment, please indicate the course number and title. If this is not a course assignment, please write "N/A"	n/a

1.6	Has another University or Institutional Research Ethics Board approved this application?	no
1.7	If YES, there is no other need to provide further details about your research at this time, provided that all of the following information is provided:1. Title of project approved elsewhere2. Name of the other institution3. Date of the decision*Please provide a copy of the application to the other institution together with all accompanying materials, as well as a copy of the approval certification.*If NO, please write "n/a" below.	n/a
1.8	Will another University REB, Institutional REB, organization or other entity (e.g. School Board, Native Band Councils, community organisations) also be asked for approval?	no
1.9	If YES, please specify which REB, organization or entity you plan to seek approval from and attach any relevant documentation to this application.If NO, please write "n/a" below.	n/a
1.10	Is this research currently being funded?	no
1.11	Will you as the researcher or any members of your research team, (including research assistants),and/or their partners or immediate family members receive any personal benefits related to this study? Examples include remuneration, patent and ownership, employment, consultanices, board membership, share ownership.	no
1.12	If YES, please describe the benefits below (for benefit to research assistants, plase provide the rate of pay). If this question does not apply please answer "n/a."	n/a
1.13	Describe any restrictions regarding access to disclosure of information (during or at the end of the study) that the sponsor has placed on you as researcher. Please write "n/a" if this does not apply to you.	n/a

2. Summary of the Proposed Research

#	Question	Answer
2.1	Research question/ Project purpose	In this study, we want to investigate how adults (18+ years of age) with Type 1 Diabetes (T1D) use their current T1D monitoring devices such as insulin pumps and glucose monitors during physical activities. Informed by such an understanding, we want to build new wearables to better support engagement in physical activities such as daily exercises and/or sports. Wearable technology or devices are smart electronic devices that can be woven into clothing or worn on the body as accessories, thereby making their usage during physical activities more comfortable.The goal for this MRP is two-parts:(A)Understand how people use their current T1D medical devices (e.g., Dexcom monitoring device which continuously tracks glucose levels, https://www.dexcom.com/continuous-glucose-monitoring) during physical activities.(B) Design alternative wearables that can help with monitoring the physical activity (e.g., heart rate, shown via multisensory feedback using audio, haptic, visual), as well as help the person take the necessary action based on the monitored data (e.g., press a button to pump more insulin).Attachment ‘Sketch’ demonstrates a scenario and two examples of such wearables.

2.2	Rationale: within 250 to 400 words, please provide the purpose and background rationale for your proposed research, including whether or not this is part of a larger project. Keeping in mind that the Research Ethics Board is a multidisciplinary including community members, please write in lay language and please provide explanations or any terms specific to your field.	T1D is an auto-immune disease in which people are dependent on pumping additional insulin into their body on a regular basis. People with T1D are often recommended to maintain proper nutrition and engage in regular physical activity to ensure their overall wellbeing. Based on our initial literature review, we found that people with T1D often times find it difficult to use their devices when taking part in physical activities. This is because of the physical form factor of the device as well as the design aesthetics of the equipment. For example, when exercising or playing sports, it is suggested to attach the insulin pumps to a strong elastic waistband with a pump case. However, such positioning can be problematic for monitoring the device or for interacting with it (i.e., pushing a button to pump additional insulin). In other instances, people have also been requested to not wear the insulin pumps so as to avoid it being accidentally knocked into the person as it can be hurtful. To address such design problems, this MRP will explore alternative wearable designs for T1D devices. Overall, to explore the two goals (understand and design) listed above, the researchers will take a two-part strategy:1. First, we will conduct interviews and brainstorm ideas for wearable devices. The collected data from the interview and brainstorming will be analyzed to inform the development of 1-2 example prototype wearable devices that meet the needs of people with T1D. [**REB approval is currently being sought for this stage**]2. Second, the built prototype will be evaluated by inviting participants to critique the strengths and limitations of the device [**REB approval for this stage will be sought via an amendment application at a later date**]. It is important to note that this

		MRP does not propose to build new medical devices, i.e., we will not build a new insulin pump. Instead, we will use existing T1D devices and build new wearables that incorporate these devices and focus on providing monitored information via multisensory feedback mechanisms and enable control of the T1D devices by the people.This MRP is not part of any other project and will be conducted and concluded within the Inclusive Design MDes program timeline (tentative end date May 2020).
2.3	Are any of the following procedures or methods involved in this study? Please check all that apply	questionnaire (e-mail)|interview (in-person)|audio taping|video taping|photography|observations|other
2.4	If you marked any methods as "other", please explain the method/s you will be using.	literature review, environmental scan, prototyping

2.5	Methodology: please describe sequentially all the methods involved in your research and all procedures in which the research participants will be involved (e.g. interviews, user testing, on-line surveys). Please provide the length of time required of participants. If your research involves different groups of participants, please distinguish between the tasks required of each	Our step-by-step procedure for conducting the first part of this research is as follows:1. We will invite volunteer adult participants to a ~1.5-hour interview and brainstorming session. Information about this study will be advertised using our flyer (attached) and participant information sheet (attached). 2. If people are interested in participating, they will email the researcher to book a suitable time for participation. 3. Prior to the study, participants will be asked to complete a short (5-6 mins) pre-study questionnaire (attached) that will collect some basic background information about the participant and the consent form. 4. On the day of the study session, the participant will engage in the following activities:a. They will first be briefly reminded of the goals of the project and their rights (20 minutes).b. The participant will next take part in a semi-structured interview (20 mins) where we will discuss their past and current positive and negative experiences of using T1D medical devices during physical activities (Goal A - understand). c. Next, the participant will be invited to take part in a brainstorming session (40 minutes) designed based on the Pictive method (Goal B - inform design). In this activity, the participant will be provided with template drawing sheets and drawing materials to sketch a few wearable devices ideas. Please see file “Attachment - Pictive Materials 1" for an example of materials and sketches. In addition to or as an alternative to sketching, participants can also showcase their prototype ideas using our physical wearable templates. Please see file “Attachment - Pictive Materials 2” for an example of prototyping materials and an example prototype. Throughout this session, participants will be encouraged to think aloud explaining their rationale.d.

		Finally, the last 20 minutes will be used to discuss the prototypes made i.e., if participants have any additional comments and/or want to make any additional changes to the prototypes and to answer any questions the participants may have. This entire session will be videotaped for posterior qualitative and quantitative analysis. The reason for the videotaping is to capture both the conversations as well as any interactions the participants may demonstrate while explaining their wearable devices.

3. Professional Expertise/Qualifications

#	Question	Answer
3.1	Does this methodology require professional expertise/recognized qualifications (e.g. registration as a clinical psychologist, first aid certification)?	no
3.2	If YES, professional expertise is needed, state what kind of professional expertise/recognized qualifications is required (e.g. registration as a clinical psychologist, first aid certification)?If NO, please write "n/a" in the space provided.	n/a
3.3	If professional expertise is needed, indicate whether you, your supervisor or any members of research team have the professional expertise/recognized qualifications required?If no professional expertise is needed, please select "not applicable".	no

4. Participants and Recruitment

#	Question	Answer

4.1	Describe the number of participants and the required demographic characteristics (such as age or gender) for each participant or participant group.	A maximum of 10 participants will be invited on a first-come-first-serve basis for the interview and brainstorming session described previously. The criteria for recruitment include participants 18+ years and above, those who have T1D, and those who occasionally and/or regularly engage in exercise routines and/or sports.
4.2	Describe how and from what sources the participants will be recruited. Provide specific details where possible (e.g. from what specific organisations, from what networks). In addition, please include any relationship between you and your research participants (e.g. family member, fellow student, instructor-student, manager-employer). Please attach a copy of any posters, advertisements and/or letters to be used for recruitment. (See attachment tab).	The participants will be recruited using:- our flyer (attached) and participant information sheet (attached) advertised on OCADU campus and local organizations such as ICD (I Challenge Diabetes) and JDRF (Juvenile Diabetes Research Foundation), - flyer and info sheet sent via INCD mailing list, - flyer and info sheet posted on public social media groups (e.g., FK Type 1 Diabetes group and College Diabetes Network group on facebook) - snowball sampling
4.3	Will participants receive compensation for participation? Please note that we do not expect Graduate Students to provide compensation.	yes
4.4	If yes, please provide details.If no, please write "n/a."	As a thank you for their time and contribution we will provide the participants with a $10 Amazon gift card.

5. Description of the Risks and Benefits of the Propo ...

#	Question	Answer
5.1	Will participants experience physical risks (including bodily contact, physical stress, eye fatigue)?	no
5.2	Will participants experience psychological risks (including feeling demeaned, embarrassed, worried, upset, or emotional stress)?	no
5.3	Will participants experience social risks (including possible loss of status, privacy and/or reputation)?	no
5.4	Are any possible risks to participants greater than those the participant might encounter in everyday life?	no
5.5	Is there any deception involved?	no

5.6	Is there potential for participants to feel obligated to participate or coerced into contributing to this research (because of regular contact between participants and the researcher or because of relationships that involve power dynamics etc)?	no
5.7	If you answered YES to ANY of the previous questions on risk, please explain the risk involved and identify its source.If you answered NO to ALL the previous questions on risk, please write "n/a" in the space provided below.	n/a
5.8	If you answered YES to ANY of the previous questions on risk, describe how each of the identified risks will be managed. Please include the availability of appropriate medical, clinical or professional expertise or qualified persons. Provide a detailed explanation of why less risky alternative approaches could not be used.If you answered NO to ALL the previous questions regarding risk, please write "n/a" in the space provided below.	n/a
5.9	Discuss any possible direct benefits to the participants from their involvement in the project. Also provide information on the potential benefits to society that would justify the involvement of participants in this study.	By taking part in this study the participants can provide direct feedback for the design and development of the next generation of wearables for T1D. This is beneficial to the participants and others in the long-term who wish to have better experiences with their T1D devices.

6. Informed Consent Process

#	Question	Answer

6.1	Describe the process you will use to introduce the Informed Consent Form, i.e. in person, by email before a face to face meeting, on-line for an on-line survey. Include information on who will be obtaining the consent, will it be you or are you delegating someone? If there will be no written consent, explain why. If applicable, attach a copy of the letter of invitation, the Consent Form and any other material that you will use in the informed consent process.	The screen readable consent forms (attached) in addition to the flyer (attached) and participant information sheet (attached) will be emailed from the researcher's student email in advance of the session. Participants will be required to read the consent forms and send back the signed consent form or bring a physical printout with them to the interview and brainstorming session.
6.2	If the participants are minors or for other reasons are not competent to consent, describe the proposed alternative source of consent including any permission form to be provided to the person(s) providing the alternative consent.If applicable, please attach a copy of the Letter of Assent and any other material to be used in obtaining consent.If this does not apply to your project, please answer "n/a."	n/a
6.3	If it is not appropriate to obtain individual participant consent BEFORE the start of this research project, please explain why and provide details for a proposed alternative consent process.If this does not apply to you, please answer "n/a."	n/a
6.4	Feedback to participants	Participants can read the MRP which will be posted publicly.

6.5	Describe how the participants will be informed of their right to withdraw from the project. Outline the procedures that will be followed to allow the participants to exercise this right.	- Participants can withdraw from the project at any time before the MRP submission deadline in May 2020. In which case their data will be deleted and not included in the MRP.- Participants are also free to refuse to continue participating in the interview and brainstorming session if they no longer feel comfortable. In which case their data will be deleted and they will still be given the $10 gift card to thank them for their time and consideration. - Participants will be informed of the above two rights in the consent form and before the start of the interview and brainstorming session.
6.6	Indicate what will be done with the participant's data should the participant choose to withdraw. Describe what consequences, if any, withdrawal might have on the participant, including any effect that withdrawal may have on participant compensation.	Captured video and the low-fidelity prototypes developed with a participant will be destroyed upon request.

7. Confidentiality and Anonymity

#	Question	Answer
7.1	Based on the provided definition, will the data be treated as confidential?	no
7.2	If you answered "no", meaning that the collected data will not be treated as confidential, please explain why there is no need to maintain privacy of the participant's data.If you answered "yes", please write "n/a" in the space below.	We will be videotaping the interview and brainstorming session to capture the conversations between the researcher and participant as well as to capture the prototypes built and their proposed interactions. This is because the video will be a useful medium to capture specific interactions. For example, a participant places the physical wearable template on their arm and shows us how it might be used during running. Such interaction scenarios would be very difficult to capture using only audio and/or researcher notes.
7.3	Based on the provided definition, are the data anonymous?	no

7.4	If you answered "yes", meaning that no one (not even the researcher) will be able to connect the data with the participants, please explain what methods you are using to ensure that anonymity of the data is maintained (such as on-line surveys with no personal information collected, drop-boxes, etc.)If you answered "no", meaning that the data are not anonymous, please write "n/a" in the space below.	n/a
7.5	Describe any personal identifiers that will be collected during the course of the research (e.g., participant names, initials, addresses, birth dates, student numbers, organizational names and titles, etc.). Indicate how personal identifiers will be secured and if they will be retained once data collection is complete.	The captured video will contain the participants' faces. At the end of the study sessions, the faces will be blurred from the video. When a video figure is created and is used to demonstrate the study session either during MRP final presentations and/or during a conference presentation, the faces of the participants will be blurred. Participants will be informed of this in their consent form. Videos that are not used for the video figure will be deleted at the end of the MRP in May 2020. The pre-interview data and any notes that were taken during the session will be assigned numeric identifiers. The collected data will be transcribed and coded for data analysis purposes. No personal identifiers such as name will be attached to the documents. The documentation will be kept secure on the OCADU student drives. Data reported in the MRP and/or publications will be discussed in aggregate form. Any specific quotes used in the MRP and/or publication will be reported using anonymous identifiers.

7.6	If any personal identifiers will be retained once data collection is complete, provide a comprehensive rationale explaining why it is necessary to retain this information, including the retention of master lists that link participant identifiers with unique study codes and de-identified data.If ALL personal identifiers will be disposed of after data collection is complete, please write "n/a" in the space provided below.	n/a
7.7	State who will have access to the data.	Only the researchers (Erman, Sowmya and Kate) will have access to the raw data. The video figure (with blurred faces) if created will be posted on the OCADU repository alongside the MRP.
7.8	Describe the procedures to be used to ensure anonymity of participants and/or confidentiality of data both during the conduct of the research and in the release of its findings.	- All participants will be identified by a numeric code (e.g., Participant 1) during the data collection, data analysis and in the release of the findings.- In the video figure, participants will not be identified with any of the identifiers (including the numeric code)- Other background information collected via a pre-study questionnaire will only be reported as an aggregate (e.g., 5 people reported using their devices during swimming)
7.9	If participant anonymity and/or confidentiality is not appropriate to this research project, explain, in detail, how all participants will be advised that data will not be anonymous or confidential.	This project will be videotaped as described above. This will be made clear in the consent form.
7.10	Explain how written records, photographs, video/audio tapes, questionnaires and digital data will be secured, and provide details of their final disposal or storage, including how long they will be secured and the disposal method to be used.	All documents will be stored on secure OCADU student drives. It will be deleted in May prior to graduation.

8. Secondary Use of Data

#	Question	Answer
8.1	Is it your intention to reanalyze the data for purposes other than described in this application?	no

8.2	If "yes", please describe the other purposes the data will be used for.If "no", please answer "n/a."	n/a
8.3	If you intend to allow the study and data to be re-analysed by colleagues, students, or other researchers outside of the original research purposes, explain how you will allow your participants the opportunity to choose to participate in a study where their data would be distributed to others. State how you will contact participants to obtain their re-consent.If this does not apply to you, please write "na/" in the space below.	n/a
8.4	If there are no plans to re-analyse the data for secondary purposes and, yet, you wish to keep the data indefinitely, please explain why.If this does not apply to you, please write "n/a" in the space below.	n/a

9. Monitoring Ongoing Research

#	Question	Answer
9.1	Indicate whether any additional monitoring or review (aside from a final report or annual progress report) would be appropriate for this project.If no additional monitoring or review is required, please write "n/a" in the space below.	n/a

Attachments

Doc / Agreement	Version Date	File Name	Description
		1- Participant Information Sheet_2 (1).pdf	Revised
		6-Flyer.pdf	N/A
Consent Material	2019/07/25	Attachment 2_ConsentForm.docx	Consent Form
Consent Material		2-ConsentForm2.docx (1).pdf	Revised

Data Gathering Instrument		Pre- Study Questionnaire.docx	Pre-study questionnaire
Data Gathering Instrument		3- Pre-Study Questionnaire.pdf	N/A
Data Gathering Instrument		4- Questions for the evaluation.pdf	N/A
Support material	2019/07/25	Attachment - Pictive Materials 2.pdf	Pictive Materials 2
Support material	2019/07/25	Attachment - Pictive Materials 1.pdf	Pictive Materials 1
Support material	2019/07/25	Flyer.pdf	FLYER
Support material	2019/07/25	Attachment 3- Questions for the interview.docx	SAMPLE QUESTIONS FOR THE SEMI-STRUCTURED INTERVIEW
Support material	2019/07/25	Attachment 1- Participant Information Sheet.docx	Participant Information Sheet
Support material		Prototype and components.pdf	Presentation with images of the prototype system.