Application 6: Human Interaction between Users and Handheld Devices

Important note: This is a real application which has been doctored for the purposes of training. Information has been removed from the application and the application has been anonymised. The UREC does not endorse this application as a model.

The application, shown on the following pages, was discussed at the workshop. A summary of the key points raised by the participants, the UREC and the original ethics reviewers follows (this is not an exhaustive list):

- The application states that ‘older’ people are to be recruited, but it is not clear how old they may be (i.e. they may be potentially vulnerable with health issues/frailty, they may not be familiar with handheld devices, may need instruction/support, may find tasks frustrating if unable to complete them etc.);

- The application does not provide much detail on exactly how the participants will be identified, approached and recruited (e.g. will permissions be obtained from third party organisations? Which organisations are to be involved? Will the researcher actually be attending events/activities to seek interested parties?);

- The application does not provide any information about the actual device to be researched and what participants will actually be required to do – this is only mentioned in the information sheet;

- The information sheet does not provide enough detail (e.g. there is no information about data protection, what will be done with the data once collected, complaints procedure, etc.);

- The application states that recorded media will be produced, but there is no mention of this on the information sheet or consent form;

- Consideration has not been given to the possibility of participants being identifiable from the videos of their hands (e.g. via tattoos, jewellery);

- No questionnaire has been included in the documentation.
Complete this form if you are a member of staff or a postgraduate research student who plans to undertake a research project which will not involve the NHS but which will involve people participating in research either directly (e.g. interviews, questionnaires) and/or indirectly (e.g. people permitting access to data and/or tissue).

or

Complete this form if you plan to submit a ‘generic’ research ethics application (i.e. an application that will cover several sufficiently similar research projects). Information on the ‘generic’ route is at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/ers.html

Documents to enclose with this form, where appropriate:
This form should be accompanied, where appropriate, by an Information Sheet/Covering Letter/Written Script which informs the prospective participants about the proposed research, and/or by a Consent Form.

Further guidance on how to apply is at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/form.html

Guidance on the three ethics review procedures that together comprise the University’s Ethics Review System (i.e. on the University’s procedure, the NHS procedure, the Alternative procedure) is at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/ers.html

Once you have completed this research ethics application form in full, and other documents where appropriate, check that your name, the title of your research project and the date is contained in the footer of each page and email it to the Ethics Administrator of your academic department. Please note that the original signed and dated version of ‘Part B’ of the application form should also be provided to the Ethics Administrator in hard copy.
University of Sheffield

University Research Ethics Application Form

Cover Sheet

I confirm that in my judgment, due to the project’s nature, the use of a method to inform prospective participants about the project (e.g. ‘Information Sheet’ / ‘Covering Letter’ / ‘Pre-Written Script’):

<table>
<thead>
<tr>
<th>Is relevant:</th>
<th>Mark 1 Box</th>
<th>Is not relevant:</th>
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I confirm that in my judgment, due to the project’s nature, the use of a ‘Consent Form’:

<table>
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<th>Mark 1 Box</th>
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<td>(if relevant then this should be enclosed)</td>
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Is this a ‘generic’ application (i.e. does it cover more than project that is sufficiently similar)?

<table>
<thead>
<tr>
<th>Yes:</th>
<th>Mark 1 Box</th>
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Date: XXXXX
Name of applicant: XXXX
Research project title: Human Interaction between Older Users and Handheld Devices
Title of Research Project:
Human Interaction between Users and Handheld Devices

A2. Contact person (normally the Principal Investigator, in the case of staff-led research projects, or the student in the case of supervised-postgraduate researcher projects):

Title: XXXX  
First Name/Initials: XXXX  
Last Name: XXXX

Post: PhD Student  
Department: XXXX

Email: XXXX  
Telephone: XXXX

A2.1. Is this a postgraduate researcher project? Yes
If yes, please provide the Supervisor's contact details:

XXXX

A2.2. Other key investigators/co-applicants (within/outside University), where applicable:
Please list all (add more rows if necessary)

<table>
<thead>
<tr>
<th>Title</th>
<th>Full Name</th>
<th>Post</th>
<th>Responsibility in project</th>
<th>Organisation</th>
<th>Department</th>
</tr>
</thead>
</table>

A3. Proposed Project Duration:
Start date: XXXX  
End date: XXXX

A4. Mark ‘X’ in one or more of the following boxes if your research:

- [ ] involves testing a medicinal product *
- [ ] involves investigating a medical device *
- [ ] involves additional radiation above that required for clinical care *
- [ ] involves taking new samples of human biological material (e.g. blood, tissue) *
- [ ] involves children or young people aged under 18 years
- [ ] involves using samples of human biological material collected before for another purpose
- [ ] involves only identifiable personal data with no direct contact with participants
- [x] involves only anonymised or aggregated data
- [ ] involves prisoners or others in custodial care (e.g. young offenders)
- [ ] involves adults with mental incapacity or mental illness
- [ ] has the primary aim of being educational (e.g. student research, a project necessary for a postgraduate degree or diploma, other than an MD or PhD)
A5. Briefly summarise the project's aims, objectives and methodology.
(this must be in language comprehensible to a lay person)

This project is to improve the usability of handheld devices. The aim of research is to investigate the hand-object interactions and the key factors that affect the sense of touch. The objective is to evaluate the usability/ergonomics of handheld devices, especially for older users.

Participants will be recruited to complete the tactile testing. This will involve informal discussion as well as written questions on perceived performance. This part of the study is expected to take a maximum of one hour for each participant. The tests may include: vibration feedback or thermal feedback, etc.

A6. What is the potential for physical and/or psychological harm / distress to participants?

There is no increased risk of physical harm to the participants. None of the tests are strenuous or dangerous.

The possibility of psychological harm is negligible for tests. All participants are free to withdraw from participation at any time without giving reason, and this is clearly explained to the participants. Questions will be related to the test procedure and will not cover any sensitive information.

A7. Does your research raise any issues of personal safety for you or other researchers involved in the project? (especially if taking place outside working hours or off University premises)

No

If yes, explain how these issues will be managed.
N/A

A8. How will the potential participants in the project be:

i. Identified?

ii. Approached?

iii. Recruited?

Participants will mainly be identified, approached and recruited through third party organisations for seniors, such as lunch groups, activity groups and social organisations. The mailing lists of these organisations, regular publications and other membership contacts will be used for publicising the research. On the other hand, participants will also be recruited through the university announcements for younger users. It will then be decided by the individual to respond or not to the advertisements for participation in the testing.

A9. Will informed consent be obtained from the participants?

YES x NO

If informed consent or consent is not to be obtained please explain why. Further guidance is at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/guidance.html
A9.1. This question is only applicable if you are planning to obtain informed consent:
How do you plan to obtain informed consent? (i.e. the proposed process?):

Informed consent will be obtained through a consent form which will be presented to the participants on arrival. The consent form will then be explained to the participant, and they will have opportunity to read the form and ask questions before signing and dating the documents to indicate consent.

A10. What measures will be put in place to ensure confidentiality of personal data, where appropriate?

The questionnaire and interview data collected will include the participant’s Age, Gender and general information about their everyday life, which will contain no personally identifiable information within it. The raw data will only be handled by the project student, or the investigators named in the table above. Any data that is published will be anonymised so that there are no personally identifiable details contained. Participants may ask that any information given be destroyed/deleted at any time.

A11. Will financial / in kind payments (other than reasonable expenses and compensation for time) be offered to participants? (Indicate how much and on what basis this has been decided)

YES [ ] NO [X]

A12. Will the research involve the production of recorded media such as audio and/or video recordings?

YES [X] NO [ ]

A12.1. This question is only applicable if you are planning to produce recorded media:
How will you ensure that there is a clear agreement with participants as to how these recorded media may be stored, used and (if appropriate) destroyed?

As a sub section to the consent form, consent to the video analysis will be given. The video data will only be focused on the hands whilst performing the task. The recorded media will be stored in a compressed and passworded archive file, on the lead researchers office computer, as well as a backup copy on a secure internet server and encrypted portable media. Access to the video files will be exclusively retained by the lead researcher. Any still frames extracted from the video files will be edited to assure anonymity for the participant before allowing access for others involved with the project (named above), or before publication. Participants may ask that any information given be destroyed/deleted at any time.

Guidance fact-sheets on ‘Safety and Well-Being’, on ‘Consent’ and on ‘Anonymity, Confidentiality and Data Protection’ are at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/factsheets.html

These three fact-sheets have been updated in the light of new findings from three Social Research Association-funded research projects, which were published in 2008, that focused on the perspective of participants regarding their experience as participants.
Title of Research Project: Human Interaction between Users and Handheld Devices

I confirm my responsibility to deliver the research project in accordance with the University of Sheffield’s policies and procedures, which include the University’s ‘Financial Regulations’, ‘Good Research Practice Standards’ and the ‘Ethics Policy for Research Involving Human Participants, Data and Tissue’ (Ethics Policy) and, where externally funded, with the terms and conditions of the research funder.

In signing this research ethics application form I am also confirming that:

- The form is accurate to the best of my knowledge and belief.
- The project will abide by the University’s Ethics Policy.
- There is no potential material interest that may, or may appear to, impair the independence and objectivity of researchers conducting this project.
- Subject to the research being approved, I undertake to adhere to the project protocol without unagreed deviation and to comply with any conditions set out in the letter from the University ethics reviewers notifying me of this.
- I undertake to inform the ethics reviewers of significant changes to the protocol (by contacting my academic department’s Ethics Administrator in the first instance).
- I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data, including the need to register when necessary with the appropriate Data Protection Officer (within the University the Data Protection Officer is based in CiCS).
- I understand that the project, including research records and data, may be subject to inspection for audit purposes, if required in future.
- I understand that personal data about me as a researcher in this form will be held by those involved in the ethics review procedure (e.g. the Ethics Administrator and/or ethics reviewers) and that this will be managed according to Data Protection Act principles.
- If this is an application for a ‘generic’ project the entire individual projects that fit under the generic project are compatible with this application.
- I understand that this project cannot be submitted for ethics approval in more than one department, and that if I wish to appeal against the decision made, this must be done through the original department.

Name of the Principal Investigator (or the name of the Supervisor if this is a postgraduate researcher project):

XXXX

If this is a postgraduate researcher project insert the student's name here:

XXXX

Signature of Principal Investigator (or the Supervisor): XXXX

Date: XXXX
**Information Sheet**

**Human interaction between users and handheld devices**

You have been invited to take part in a research topic here at the University of Sheffield. Your participation in the research is entirely voluntary, and you may withdraw at any time without giving a reason. You may also request that any information/recordings be destroyed at any times. All information you give will be kept strictly confidential.

*What is the aim of the study?*

This project is to improve the usability of handheld devices. The aim of research is to investigate the hand-object interactions and the key factors that affect the sense of touch. The objective is to evaluate the usability/ergonomics of handheld devices, especially for older users.

*What will participation in the study involve?*

The test is to evaluate the tactile effect of mobile phones. Participants will be asked to put fingers onto a simulated version of a touchscreen which will vibrate and provide feedback to the user in different ways. Certain information about the participants (e.g. age and gender) will be collected but this will all be anonymised. Finally, participants will be asked to fill in questionnaires about their experiences during the study.

*Who has reviewed the study?*

This research has been reviewed by the Ethics Committee of the Department of XXXX, University of Sheffield.

*Further Information*

If you require any further information, please contact:

XXXX
Title of Project: Human interaction between users and handheld devices

Name of Researcher: XXXX

Participant Identification Number for this project:

Participant ID Number for Questionnaire (if applicable):

Please initial box

iv. I confirm that I have read and understood the information sheet for the above project and have had the opportunity to ask questions. □

v. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. I may also request that my data be deleted at any time. □

vi. I understand that my responses will be anonymised before analysis. I give permission for members of the research team to have access to my anonymised responses. □

vii. I agree to take part in the above project. □

_________________________________________  __________________________  _________________
Name of Participant                  Date                      Signature

_________________________________________  __________________________  _________________
Researcher                          Date                      Signature

Copies:
One copy for the participant and one copy for the Principal Investigator / Supervisor.