

# Ethical Review Form Education

(Version 17.07.2020)

This Ethical Review Form should be completed for every research study that involves human participants or personally identifiable data. The form should be submitted and approved by your supervisor before potential participants are approached to take part in the research study.

## Part 1: General Study Information

<b>1</b>	Student name and email	D.A. Muilenburg (Delmar), <a href="mailto:d.a.muilenburg@student.tue.nl">d.a.muilenburg@student.tue.nl</a> J.A. Nagelhout (Arjo), <a href="mailto:j.a.nagelhout@student.tue.nl">j.a.nagelhout@student.tue.nl</a> J.T.M. Grandia (Janiek), <a href="mailto:j.t.m.grandia@student.tue.nl">j.t.m.grandia@student.tue.nl</a> T.F.M. Maessen (Timo), <a href="mailto:t.f.m.maessen@student.tue.nl">t.f.m.maessen@student.tue.nl</a>
<b>2</b>	Supervisor name and email	R. Bernhaupt (Regina), <a href="mailto:r.bernhaupt@tue.nl">r.bernhaupt@tue.nl</a> G. Wallner (Günter), <a href="mailto:g.wallner@tue.nl">g.wallner@tue.nl</a>
<b>3</b>	Degree Program	Industrial Design
<b>4</b>	Bachelor/master	Bachelor
<b>5</b>	Bachelor/master end project?	No
<b>6</b>	Course name and code	Games and play, DEP005
<b>7</b>	Project title	A playful tool for increasing citizen participation in urban design and planning (Games for Data Collection)
<b>8</b>	Research location	Eindhoven
<b>9</b>	Research period (start/end date)	The study will be performed over the timespan of 2020/11/09 to 2021/01/15.
<b>10</b>	[If Applicable] Proposal already approved by (external) Ethical Review Board: Add name, date of approval, and contact details of the ERB	No
<b>11</b>	Research question	How can we give form to and test the effectiveness of a platform that aims to increase citizen participation in urban design and planning through the use of gamification and location-based augmented reality?
<b>12</b>	Description of the research method	<i>What will the participants be asked to do for the study?</i> In the study participants will be asked to take part in a user test so that we can get qualitative data on the effectiveness of certain parts of our product. This will be done through letting users interact with our prototype. Additionally, anonymous quantitative data is collected through our prototype to get insight in user flow, user retention and other performance metrics.  To gain insight into the needs of our target group and the desirability or relevance of our problem and product, both quantitatively and qualitatively, we will conduct interviews and create questionnaires.
<b>13</b>	Description of the research population, in- and exclusion criteria	<i>Describe the participants of your research. What characteristics do they have? Who is eligible and who will be excluded?</i> We try to create a product that is inclusive to a wide range of the population - given they have access to the required technology. Because of this we want to target the following age segments: young adults, adults and elderly people. We also want to target people with proficiency in 3D design and/or augmented reality. This way we can achieve a product that allows for both intuitiveness and expressiveness.

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14	Number of participants	<p><i>How many participants do you need to answer the research question?</i></p> <p>For the user tests and interviews we aim to get at least 4 people from each target group (adults, young adults, elderly, people proficient with 3D design or augmented reality), giving a total number of participants of 16-24. For the questionnaires a larger sample is aimed for: 20-80.</p>
15	Explain why the research is socially important.	<p><i>Why is the research important for society? Is there also any possible harm for society?</i></p> <p>Our living environment has great influence on our wellbeing. Greenery, places to hang out, cleanliness and variation are key elements to creating a positive environment for people to be in. Next to that, a sense of community and responsibility in their neighbourhoods further improves this.</p> <p>We see an opportunity to make the process of urban design and planning in neighbourhoods more creative, inclusive and fun.</p> <p>This way, people are more engaged and motivated for the planning and design of their environment. Next to that, communication among municipalities and citizens is then predicted to improve, as well as having people feel more connected to their neighbourhood and living environment.</p>
16	Describe the way participants will be recruited	<p><i>How will the participants be found and contacted?</i></p> <p>Participants will be recruited through the means of our personal network, as well as reaching out through online channels such as Facebook groups, communities on Reddit and other Internet forums.</p>
17	Provide a brief statement of the risks you expect for the participants or others involved in the research and explain. Take into consideration any personal data you may gather and privacy issues.	<p><i>Are there any risks involved for the participants or others involved in the study? Think about what participating in the study will entail for them, what type of data you will collect and how you will make sure these data will be kept safe</i></p> <p><i>There are no risks</i> associated with participating in the study. We will, however, capture video as part of the user tests, this data is not distributed outside of our project team and stored on a secure storage medium at TU/e. The video's will be analysed through different performance metrics and transcribed. After this process has been completed for a given video, the video will be permanently destroyed. Other personally identifiable data is not required for our study and will be reported in an anonymized fashion.</p>

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<b>Part 2: Checklist for Minimal Risk</b>			
		<b>Yes</b>	<b>No</b>
<b>1</b>	<p>Does the study have a medical scientific research question or claim (see definition below)</p> <p><i>Medical/scientific research is research which is carried out with the aim of finding answers to a question in the field of illness and health (etiology, pathogenesis, signs/symptoms, diagnosis, prevention, outcome or treatment of illness), by systematically collecting and analysing data. The research is carried out with the intention of contributing to medical knowledge which can also be applied to populations outside of the direct research population.'</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes or maybe: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval	If no: Continue with question 2
<b>2</b>	Does the study involve human material (such as surgery waste material derived from non-commercial organizations such as hospitals)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes or maybe: This is only allowed if your supervisor has consulted with the medical coordinator. Continue with question 3	If no: Continue with question 3
<b>3</b>	Will the participants give their explicit consent – on a voluntary basis – either digitally or on paper? Or have they given consent in the past for the purpose of education or for re-use in line with the current research question?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		If yes: Continue with question 4	If no: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval
<b>4</b>	Will the study involve discussion or collection of personal data? (e.g. name, address, phone number, email address, IP address, BSN number, location data) or will the study collect and store videos, pictures, or other identifiable data of human subjects?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		If yes: The handling, storing and de-identification of the personal data should be discussed with your supervisor. Continue with question 5 if you met all requirements for handling personal data (see ...)	If no: Continue with question 5

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		Yes	No
5	Does the study involve participants who are particularly vulnerable or unable to give informed consent? (e.g. children, people with learning difficulties, patients, people receiving counselling, people living in care or nursing homes, people recruited through self-help groups)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval	If no: Continue with question 6
6	May the research procedure cause harm or discomfort to the participant in any way? (e.g. causing pain or more than mild discomfort, stress, or anxiety)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval	If no: Continue with question 7
7	Will the participants receive any compensation for their participation? Such as a coupon or a chance to win a prize?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval	If no: Continue with question 8 or 10, depending on the type of study (see red text below)
<b>The following questions 8-9 are for <i>observational</i> research (e.g. (semi-)structured interviews; focus groups; (participatory) observations). If your research is <i>experimental</i>, then skip questions 8-9 and continue with question 10</b>			
8	Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g. covert observation of people)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes: This is only allowed when observing behavior in public space. If so, continue with question 9. If you observe people in non-public space without their consent, your supervisor should submit the study to the ERB. You cannot get automatic ethical approval	If no: Continue with question 9
9	Will participants be asked to discuss or report sexual experiences, religion, alcohol or drug use, or suicidal thoughts, or other topics that are highly personal or intimate?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval	If no: Continue with part 3

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The following questions 10-13 are for *experimental* research (e.g. measurements on yourself or another person; testing a prototype/device; influencing behavior through manipulation (e.g. light or temperature)). If your research is *observational*, then skip questions 10-13 and continue with part 3

		Yes	No
10	Is the study invasive (i.e. it affects the body such as puncturing the skin; taking blood or other body material (such as DNA) from the participant)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval	If no: Continue with question 11
11	Does the device have a medical purpose such as diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease or injury?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes or maybe: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval	If no: Continue with question 12
12	Will the experiment involve the use of physical devices that are 'CE' certified for unintended use (meaning you will use existing CE certified devices for other things than they were originally intended for)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes: This is only allowed if they are completely harmless. They should have a harmless voltage of <5V and hazardous waste (fumes/gas/substances) should not be released. You should discuss with your supervisor whether you need to have the device tested for safety	If no: Continue with question 13
13	Will the experiment involve the use of physical devices that are not 'CE' certified?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		If yes: This is only allowed if they are completely harmless. They should have a harmless voltage of <5V and hazardous waste (fumes/gas/substances) should not be released. You should discuss with your supervisor whether you need to have the device tested for safety	If no: Continue with part 3

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### Part 3: Enclosures and Signature

1	<p>Enclosures (tick if applicable):</p> <p><input checked="" type="checkbox"/> Informed consent form (link to template);</p> <p><input checked="" type="checkbox"/> The survey the participants need to complete, or a description of other measurements (such as interview questions or a description of the prototype);</p> <p><input type="checkbox"/> Text used to find participants (such as brochures, flyers, etc);</p> <p><input type="checkbox"/> Approval other research ethics committee;</p>	<p>Informed consent form - User test: <a href="https://docs.google.com/document/d/1se9tDzl29A8uJEyCknYtDH-PpHgau1QZbFk6Efg3NE0/edit?usp=sharing">https://docs.google.com/document/d/1se9tDzl29A8uJEyCknYtDH-PpHgau1QZbFk6Efg3NE0/edit?usp=sharing</a></p> <p>Informed consent form - Interview: <a href="https://docs.google.com/document/d/1DHti7IUivu4iw4eahjlCxHYUGz8CkHRdBcCea-7_140/edit?usp=sharing">https://docs.google.com/document/d/1DHti7IUivu4iw4eahjlCxHYUGz8CkHRdBcCea-7_140/edit?usp=sharing</a></p> <p>Informed consent form - Quantitative data collection through application <a href="https://docs.google.com/document/d/1lp12fmPOqWuYIX79uWSrvVc9oRkWMqKZHF_K2p97vdk/edit?usp=sharing">https://docs.google.com/document/d/1lp12fmPOqWuYIX79uWSrvVc9oRkWMqKZHF_K2p97vdk/edit?usp=sharing</a></p> <p>Informed consent form - Questionnaire <a href="https://docs.google.com/document/d/101bDbkwpdco94GIP0tYqeceZAeBARhtz56EhzGjOg/edit?usp=sharing">https://docs.google.com/document/d/101bDbkwpdco94GIP0tYqeceZAeBARhtz56EhzGjOg/edit?usp=sharing</a></p>
2	<p>I hereby declare that I have completed this form truthfully</p> <p>Signature(s) of the student(s)</p> <p>Date</p>	

Discuss this form with your supervisor. If any of the boxes you ticked in Part 2 suggest that your supervisor should submit your study to the ERB for ethical approval, try to change your research design in such a way that your supervisor can approve it instead. If this is not possible, ask your supervisor to submit the proposal to the ERB. It will take two to five weeks before you receive a decision from the ERB.

### Part 4: Review by supervisor

		Yes	No
1	<p>Does the data storage adhere to all requirements of responsible data management (link toevoegen)?</p>	<input type="checkbox"/>	<input type="checkbox"/>
		<p>If yes: Continue with question 2</p>	<p>If no: Discuss with your student the necessary steps to adhere to the requirements</p>
2	<p>Does the research proposal adhere to all requirements for automatic approval?</p>	<input type="checkbox"/>	<input type="checkbox"/>

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		If yes: Please skip the questions 3-6 and sign the form	If no: Discuss with your student if any alterations can be made in order to adhere to the requirements for automatic approval. If you decide that the study cannot adhere to the requirements, then you as a supervisor need to submit the proposal to the ERB. Please answer the following additional questions (3-6)
<b>Additional questions for ERB approval</b>			
<b>3</b>	Elaborate on the topics from part 2 that do not allow for automatic approval. Describe how you safeguard any potential risk for the research participant for each topic.		
<b>4</b>	Describe and justify the number of participants you need for this research, taking into account the risks and benefits		
<b>5</b>	Explain if your data are completely anonymous, or whether they will be de-identified (pseudonymized or anonymized) and if so, explain how		
<b>6</b>	Who will have access to the data?		

<b>Part 5: Signature by supervisor</b>	
<p>I hereby declare that I have completed this form truthfully</p> <p>Signature of the supervisor</p>	

# Ethical Review Form

Date	
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