Ethical Review Form

(Version 27.06.2019)

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

Part 1: General Study Information

1	Project title	Generative Sessions with Design Students and Staff (Note: this is an application for collective approval of a well specified set of activities- staff conducting such studies will self-check compliance using the checklist provided as an ammendment)
2	Researcher	P.Markopoulos
3	Email researcher	P.Markopoulos@tue.nl
4	Supervisor(s)	N/A
5	Faculty/department	Industrial Design
6	Research location	TU/e campus or using secure remote collaboration tools supported by the TU/e (e.g. MS Teams, Canvas, Skype for Business).
7	Research period (start/end date)	April 1 2020 / December 31 2022
8	Funding agency	Variable: this application applies both to funded and non-funded research or research done for educational purposes.
9	[If Applicable] Study is part of an educational course with code:	N/A
10	[If Applicable] Proposal already approved by external Ethical Review Board: Add name, date of approval, and contact details of the ERB	N/A
11	Short description of the research question	What are suitable ideas and concepts to address a given design challenge? How do participants behave and how do they experience and reflect upon the creative session?
12	Description of the research method	A generative session where participants ideate and create representations of design ideas and situations.
13	Description of the research population, exclusion criteria	Participants are adults students and staff and non-vulnerable adults participating voluntarily in design activities.
14	Description of the measurements and/or stimuli/treatments	Representations of ideas and concepts. Artefacts participants create Observations and recordings of design rational and reflections. Quantifiable self-reports on the quality of the design process.
15	Number of participants	Between 1 and 30. Typically sessions will involve 4-7 participants, which is a suitable number for different generative techniques. Multiple sessions will be organized when large number of participants are needed.
16	Explain why the research is socially important. What benefits and harm to society may result from the study?	Generative design activities are essential in the education and the research activities of industrial design. This collective application is essential to ensure flexible design processes which are key to the way of working of industrial designers. It provides a framework within which generative activities can proceed with minimal procedure and be aligned with ethical regulation.

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17	Provide a brief statement of the risks you expect for the participants or others involved in the research or educational activity and explain. Take into consideration any personal data you may gather and privacy issues.	Misunderstandings may emerge regarding ownership of ideas. Audi-video recordings are private data which should be treated appropriately. (e.g. to not disclose extracts out of context or causing embarrassment)

Part 2: Checklist for Minimal Risk

		Yes	No
1	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)		X
2	Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children or own students)?	X	
3	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 in non-public places)		X
4	Will the study involve actively deceiving the participants? (e.g. will participants be deliberately falsely informed, will information be withheld from them or will they be misled in such a way that they are likely to object or show unease when debriefed about the study)		X
5	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?[1]. Please check the FAQ's on the intranet. If yes: please follow the procedure. Make sure you perform a Data Protection Impact Assessment (DPIA) and make a Data Management Plan if necessary and let the data steward check it.	X	
6	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?		X
7	Will participating in the research be burdensome? (e.g. requiring participants to wear a device 24/7 for several weeks, to fill in questionnaires for hours, to travel long distances to a research location, to be interviewed multiple times)?		X
8	May the research procedure cause harm or discomfort to the participant in any way? (e.g. causing pain or more than mild discomfort, stress, anxiety or by administering drinks, foods, drugs)		X
9	Will blood or other (bio)samples be obtained from participants (e.g. also external imaging of the body)?		X
10	Will financial inducement (other than reasonable expenses and compensation for time) be offered to participants?	X	
11	Will the experiment involve the use of physical devices that are not 'CE' certified?		X

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Important: If you answered all questions with ''no'', you can skip parts 3 - 4 and go directly to part 5. Check which documents you need to enclose and continue with signature and submission. If you answered one or more questions with "yes", please continue with parts 3 – 5.		
Part 3: Study Procedures and Sample Size Justification		
1	Elaborate on all boxes answered with "yes" in part 2. Describe how you safeguard any potential risk for the research participant.	**Box 2:** Students and participating staff may be at a subordinate position to the staff member organizing a creative session. In such cases, participation must be equitable and voluntary. We request approval for: 1) cases where the participants are not in dependent/subordinate position 2) where there is such a relation, participation should be equitable and voluntary, including the option to drop out of the study at any time. Equitable means that it should be demonstrated to provide appropriate educational benefits, or includes reciprocity/community participation (students helping each other), is serving a shared cause (e.g. to achieve a common aspiration) or is compensated adequately (e.g., by paying participants according to the TU/e norms or donating similar amounts to recognized charities). **Box 5.** Audio-video records will be created with consent and adherence to GDPR only when these will be necessary for reporting the study in scientific venues. Otherwise recording will be avoided. They will be stored anonymously and securely and kept for 5 years. **Box 10.** Financial inducement will be provided following the university norms for student participation in behavioural studies.
2	Describe and justify the number of participants you need for this research or educational activity. Also justify the number of observations you need, taking into account the risks and benefits	The number of participants is variable; at different steps of the design process different numbers of people may need to be involved. There are no hard rules for this, and a small or large number of participants cannot be prescribed to ensure the quality of the results. However, the number of participants in the session may create logistics issues, and the designer needs to be able to manage those to ensure good use of the participant time (e.g., enough materials, opportunity for all to contribute, avoiding dominating behaviours and group think). Where appropriate, multiple creative sessions will be organized to split larger number of participants in manageable groups.

Part 4: Data and Privacy Statement		
1	Explain whether your data are completely anonymous, or if they will be de-identified (pseudonymized or anonymized) and explain how	
2	Who will have access to the data?	

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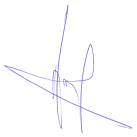
3	Will you store personal information that will allow participants to be identified from their data? See VSNU draft.	☐ No ☒ Yes, and I declare I will follow the general data protection regulation (GDPR).
4	Will you share de-identified data (e.g., upon publication in a public repository)?	☐ No ☒ Yes, and I will inform participants about how their data will be shared, and ask consent to share their data. I will, to the best of my knowledge and ability, make sure the data do not contain information that can identify participants.

Part 5: Closures and Signatures

1	Enclosures (tick if applicable): ☐ Informed consent form; ☐ Informed consent form for other agencies when the research is conducted at a location (such as a school); ☐ Text used for ads (to find participants); ☐ Text used for debriefings; ☐ Approval other research ethics committee; ☒ Any other information which might be relevant for decision making by ERB; ☐ Data Protection Impact Assessment checked by the privacy officer ☐ Data Management Plan checked by a data steward	A checklist is provided for self-assessment. Students or staff may determine whether they are covered by this collective ERB application.
2	Signature(s) Signature(s) of researcher(s) Date: Signature research supervisor (if applicable) Date:	 8.3.2020