UNIVERSITY OF Southampton

Ethics Application Form for SECONDARY DATA ANALYSIS

Please consult the guidance at the end of this form before completing and submitting your application.

1. **Name(s):** Pier Paolo Ippolito

2. **Current Position:** 3rd Year Undergraduate Student.

3. **Contact Details:**

   Division: Electronics and Computer Science

   Email: ppi1u16@soton.ac.uk

   Phone: 07904579210

4. **Is your research being conducted as part of an education qualification?**

   Yes ☒   **No** ☐

5. **If Yes, please give the name of your supervisor:**

   Koushik Maharatna

6. **Title of your research project / study:**

   Alleviate Children's Health Issues through Games and Machine Learning

7. **Briefly describe the rationale, aims, design and research questions of your research**

   Please indicate clearly whether you are applying for ethics approval for a specific piece of research, or for overarching ethics approval to use certain datasets for a range of research activities. Approval for the latter will only cover the datasets specified here, for a maximum of 3 years and then subject to renewal.

   This research aims to make use of the data carried out during the "Fusiform Gyrus responses to neutral and emotional faces in children with Autism Spectrum Disorders: a High Density ERP study" to use Machine Learning for classification purposes such us identifying if a child is affected or not by disabilities analysing the data-set input features (eg. EEG signals, no personal data). Fully anonymised data.

8. **Describe the data you wish to analyse**

   Please give details of the title of the dataset, nature of data subjects (e.g. individuals or organisations), thematic focus and country/countries covered. Indicate whether the data are qualitative or quantitative, survey data, administrative data or other types of data. Identify the source from where you will be obtaining the data (including a web address where appropriate).

   The dataset used will make use the data carried out during the: "Fusiform Gyrus responses to neutral and emotional faces in children with Autism Spectrum Disorders: a High Density ERP study" (https://www.ncbi.nlm.nih.gov/pubmed/23124137). Children affected by Autism Spectrum Disorders (ASD) typically show early and severe impairments in understanding social and emotional information conveyed by faces. This study aimed to show to a group of children (some of which were affected by ASD and some who didn't) a

sequence of stimulus (eg. images of happy faces, sad faces, etc..) and to record their EEG response for later analysis.

9. **What are the terms and conditions around the use of the data? Did data subjects give consent for their data to be re-used? If not, on what basis is re-use of the data justified?**

Please state what (if any) conditions the data archive imposes (e.g. registration, signing of confidentiality agreement, specific training etc.). In many cases the data controller will have given explicit permission for data re-use. Please explain how you justify the use of data if approval and consents for the original data collection and re-use are not in place. This may be the case where, for example, the original data collection predated requirements for ethics review or occurred in a jurisdiction where explicit consent and approval are not required.

Concerning the dataset, written informed consent was obtained in all cases by parents of all the children who took part in this study. The only requirement is to acknowledge and cite the original data. There are no other restrictions. As the data are fully anonymised, there is no GDPR compliance issue. The dataset will be provided by the project supervisor (Koushik Maharatna).

10. **Do you intend to use personal data (https://ico.org.uk/media/1549/determining_what_is_personal_data_quick_reference_guide.pdf) or sensitive personal data (http://www.legislation.gov.uk/ukpga/1998/29/section/2) as defined by the Data Protection Act (even if the data are publicly available)?**

Yes ☐ **No** ☒

If YES, please specify what personal data will be included and why.

11. **Do you intend to link two or more datasets?**

Data linkage refers to merging of information from two or more sources of data to consolidate facts concerning an individual or an event that are not available in any separate record. Please note that for the purposes of research ethics we are not interested in the merging of different waves of a particular survey, or the merging of data from different countries for the same survey.

Yes ☐ **No** ☒

If YES, please give details of which datasets will be linked and for what purposes.

12. **How will you store and manage the data <u>before</u> and <u>during</u> the analysis? What will happen with the data <u>at the end of</u> the project?**

Please consult the University of Southampton's Research Data Management Policy (http://library.soton.ac.uk/researchdata/storage and http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html), and indicate how you will abide by it.

Data will be downloaded to a virtual machine provided by the university and accessed via my laptop. At the end the project the data will be given back to the project supervisor (Koushik Maharatna).

13. **How will you minimise the risk that data subjects (individuals or organisations) could be identified in your presentation of results?**

Please consider whether disclosive ID codes have been used (e.g. date of birth) and whether it is theoretically possible to identify individuals by combining characteristics (e.g. widow in Hampshire with 14 children) or by combining datasets. How will you protect individuals' anonymity in your analysis and dissemination?

The data I will be given will be fully anonymised. There is no possibility to identify data subjects (No way to relate data to patients). I have never been in direct contact with the patients, and I haven't been involved in carrying out the measurement.

14. **What other ethical risks are raised by your research, and how do you intend to manage these?**

    Issues may arise due to the nature of the research you intend to undertake and/or the subject matter of the data. Examples include: data or analysis that are culturally or socially sensitive; data relating to criminal activity, including terrorism, and security sensitive issues.

    None.

15. **Please outline any other information that you feel may be relevant to this submission.**

    For example, will you be using the services or facilities of ONS, ADRN, or HSCIC and/or are you obtaining ethical review from NRES (through IRAS) or other? Please confirm whether the data being used are already in the public domain.

    None.

16. **Please indicate if you, your supervisor or a member of the study team/research group are a data controller and/or data processor in relation to the data you intend to use as defined by the Data Protection Act, and confirm that you/they understand your/their respective responsibilities https://ico.org.uk/for-organisations/guide-to-data-protection/key-definitions/.**

    The controller and processor are defined by the information commissioner's office as follows:

    - A controller determines the purposes and means of processing personal data.
    - A processor is responsible for processing personal data on behalf of a controller.

    Since no personal data is being used in this study, we are neither the controller or the processor.

Note: This Ethics Application Form is currently being piloted. If you have comments on any of the questions, it would be helpful if you could email them to rgoinfo@soton.ac.uk with "Secondary Data Analysis Form" in the subject line.

Guidance on applying for ethics approval for secondary data analysis

If your research PURELY involves the following, you do <u>not</u> need to apply for ethics approval:

- analysis of <u>aggregated</u> data on individuals or organisations (e.g. GDP, labour force participation rates, fertility rates);
- meta-analyses (i.e. the analysis of studies);
- literature reviews or reviews/analyses of reports, policies, documents, meeting minutes, newspaper articles, films.

<u>Filling in the online submission form on ERGO II:</u>

- Please give your application a title that includes 'SDA' (Secondary Data Analysis).
- Please refer to the "**ERGO II Guidance for Applicants**" document (downloadable from the ERGO II site) on how to answer the submission questionnaire correctly..

<u>Additional Forms:</u>

If your study PURELY involves secondary analysis of data, you only need to fill in the 'Ethics Application Form for Secondary Data Analysis'. You do not need a Risk Assessment Form.

If your study is a mixed-method study involving secondary data analysis AND some component of data collection (e.g. interviews, online survey), then you need to fill in additional forms:

- Ethics Application Form (for studies other than secondary data analysis)
- Risk Assessment Form
- Participant Information Sheet
- Consent Form
- Draft research instrument

<u>Please note:</u>

- <u>You must not begin data analysis until ethical approval has been obtained</u>.
- It is your responsibility to follow the University of Southampton's Ethics Policy and any relevant academic or professional guidelines in the conduct of your research. This includes ensuring confidentiality in the storage and use of data.
- It is your responsibility to provide <u>full and accurate information</u> in completing this form.