Application for Ethical Approval

of PPLS Research

Email address of applicant
Hugh.Rabagliati@ed.ac.uk

1.1 *Title of Study*

1.2 *Type of Project*

1.2.1 *If the student is in LEL, has the student completed the online Ethics Training Module*

1.2.2 *If training has been completed, what was the completion date for the ethics training*

1.3a *Applicant Details*

1.3b *Name of all University of Edinburgh collaborators and their roles on this project*

Role	Forename/Initials	Surname	UUN	E-mail
	Unknown	Unknown		Unknown
	Unknown	Unknown		Unknown
	Unknown	Unknown		Unknown

1.4 *If applicable, give the names, email addresses, and institution of any collaborator(s) outwith the University of Edinburgh and their research roles on this project*

Full name	E-mail	Institution

1.5 *What subject area / group best matches your project*

1.6 *Is another ethics committee outside of PPLS reviewing this project*

1.6.1a *Describe the status of the application at each other institution or ethics committee*

1.6.1b *Give the details of the current status of that application if not yet approved*

1.6.2a *Does this research Involve NHS patients/service users or their carers: access to data, organs or other materials from past of present NHS patients; foetal or IVF material from NHS patients; recently dead NHS patients*

1.6.2b *Does this research Involve, take place in, or use facilities of the NHS*

1.6.2c *Does this research Involve clinical trials*

1.6.3 *Have you consulted the Universities Research Governance and NHS R&D Office to get appropriate approvals and costs*

1.7 *Is there a funding body for the project*

•	*If there is a funder, who is the funder? Does the funder require formal prior ethical review? If yes, by what date is a response for the prior review required*
1.8a	*Project Start date*
1.8b	*Anticipated end date of data collection or project completion*
1.9a	*Does this research project involve human or other live participants*
1.9b	*Does this research project make use of any ethically sensitive pre-existing data*
1.9bi	*If using pre-existing material, what is the source of your pre-existing material*
•	
1.9c	*Does this research project concern groups that may be construed as terrorist or extremist in any way*
1.9d	*I hereby declare that I am familiar with the usage guidelines of my data source, or will familiarise myself with the guidelines prior to beginning my project*
1.9e	*Are you planning on carrying out on-campus or off-campus face-to-face research*
2.1B.1	*Please describe the source of your pre-existing data*
2.1B.2	*Please describe how you have obtained permission to use this data*
2.1B.3a	*Was the data collected under an existing PPLS research ethics protocol*
2.1B.3b	*Reason why unable to add name to existing PPLS data*
2.1C.1	*Please describe the source of your pre-existing data*
2.1C.2	*What are the usage guidelines of your data source, if known*
2.1C.3	*What are the main objectives of your study*
2.1C.4	*Is there any potential for the confidentiality of the contributors to your pre-existing data to be compromised*
2.1C.5	*How feasible is it to obtain consent from the contributors to your pre-existing data, and will you be obtaining their consent*

2.1C.6	*If any information is likely to be passed on to external companies or organisations in the course of the research, please describe. If the project is a funded collaboration with an external company, please give that information here*
2.1C.7	*Does your research involve a conflict of interest or any situation which could be construed as a conflict of interest*
2.1C.8	*Could any aspect of the proposed research bring the University into disrepute*
2.1CD.1	*Please describe the source of your pre-existing data*
2.1CD.2	*What are the usage guidelines of your data source, if known*
2.1CD.3	*Is there any potential for the confidentiality of the contributors to your pre-existing data to be compromised*
2.1CD.4	*How feasible is it to obtain consent from the contributors to your pre-existing data, and will you be obtaining their consent*
2.1D.1	*Briefly describe the main objectives of your study*
2.1D.2	*What methods are you using for your study*
2.1D.3a	*Who are your participants? What criteria will be used in deciding on the inclusion and exclusion of participants in the study*
2.1D.3b	*How will you recruit your participants? How many will you aim to recruit*
2.1D.3c	*Does the study involve a 'gatekeeper'*
•	*If you have a gatekeeper, please describe.*
2.1D.4a	*What will your participants be asked to do for your study, and where will you see them/test them*
2.1E.4b	*If you or any study researchers are collecting data in locations where your or their safety could be compromised, explain how you will deal with this*

2.1D.5a	*How will consent be obtained (by the person able to consent on behalf of the participant, if the participant is unable)*
2.1D.5a.1	*If no consent will be obtained, explain what information will be collected, how it will be collected, why lack of direct consent is necessary, and how potential risk will be mitigated*
2.1D.5a.2	*If other, please specify*
2.1D.5b	*Will participants be given an information sheet separate from obtaining consent*
2.1D.6	*Are you gathering (potentially) identifiable information about participants*
2.1D.6a	*What (potentially) identifiable information are you gathering*
2.1D.6b	*Will the information include special categories of personal data*
2.1D.6b.1	*Explain what safeguards e.g. technical or organisational you have in place*
2.1D.6b.2	*Please indicate how your research is in the public interest*
2.1D.6b.2b	*If other, explain how your research is in the public interest*
2.1D.6c	*Please identify all risks to the privacy of research participants resulting from collection of identifiable data in your study. Then consider and indicate the likelihood of the risks actually manifesting and the severity of harm if the risks actually manifest*
•	*Likelihood of risk manifesting: Identifiable due to data linkage*
•	*Severity of harm: Identifiable due to data linkage*
•	*Likelihood of risk manifesting: Identifiable due to location*
•	*Severity of harm: Identifiable due to location*
•	*Likelihood of risk manifesting: Identifiable due to low participant numbers*
•	*Severity of harm: Identifiable due to low participant numbers*

•	*Likelihood of risk manifesting: Identifiable due to data access breach*
•	*Severity of harm: Identifiable due to data access breach*
•	*Description of Risk: Other (1)*
•	*Likelihood of risk manifesting: Other (1)*
•	*Severity of harm: Other (1)*
•	*Description of Risk: Other (2)*
•	*Likelihood of risk manifesting: Other (2)*
•	*Severity of harm: Other (2)*
•	*Description of Risk: Other (3)*
•	*Likelihood of risk manifesting: Other (3)*
•	*Severity of harm: Other (3)*
•	*Description of Risk: Other (4)*
•	*Likelihood of risk manifesting: Other (4)*
•	*Severity of harm: Other (4)*
2.1D.6d	*If you have identified risks which are possible or probable and, if manifest, either significant or severe, please explain in more detail, and identify measures you will take to reduce or eliminate these risks*
2.1D.6e	*How will the identifiable data (including consent forms) be stored during the data collection period? What will happen to the data after the data collection period has finished? How will you maintain secure storage of this data? What data formats will you use to ensure long-term usability*
2.1D.6f	*How will the identifiable data be used? Who will have access to them? How will you share them? How will participants be informed about these issues*

2.1D.6g	*Will information containing personal and/or identifiable data be transferred to, shared with, supported by, or otherwise available to third parties outside the University*
2.1D.6h	*Other than the use by third parties under the section above, will the data be used, accessed or stored away from University premises*
2.1D.7	*Are you collecting non-identifiable data*
2.1D.7a	*What non-identifiable data are you collecting*
2.1D.7b	*How will this non-identifiable data be stored during the data collection period? What will happen to the data after the data collection period has finished? How will you maintain secure storage of your data? What data formats will you used to ensure long-term usability*
2.1D.7c	*How will this non-identifiable data be used? Who will have access to it? How will you share it? How will participants be informed about these issues*
2.1D.7d	*If any non-identifiable information is likely to be passed on to external companies or organisations in the course of the research, please describe. If the project is a funded collaboration with an external company, please give that information here*
2.1D.8	*Explain how you will allow participants to withdraw from the study after data collection and specify a date*
2.1D.9	*How will you ensure that potential participants do not feel compelled or coerced into taking part*
2.1D.10	*How will the data be fed back to the public*
2.1D.11	*Does your research involve a conflict of interest or any situation which could be construed as a conflict of interest*
2.1D.12	*Could any aspect of the proposed research bring the University into disrepute*
2.1D.13a	*Vulnerable participants*
2.1D.13b	*Potential psychological stress or discomfort to participants, beyond the risks encountered in everyday life*
2.1D.13c	*Physically invasive or potentially physically harmful procedures*
2.1D.13d	*Pain more than mild discomfort*

2.1D.13e *The investigation of any illegal behavior*

2.1D.13f *The investigation of highly sensitive topics*

2.1D.13g *A real risk of disclosure of activities which should be reported to the authorities*

2.1D.13h *Deception*

2.1D.13i *Risk to the researcher(s)*

2.1E..1a *Under 16 years of age*

2.1E.1b *In the care of a Local Authority*

2.1E.1c *Known to have special educational needs*

2.1E.1d *Physically or mentally ill*

2.1E.1e *Members of a vulnerable or stigmatized minority*

If members of a vulnerable or stigmatized minority, please describe

2.1E.1f *Vulnerable in other ways*

If vulnerable in other ways, please describe

2.1E.1g *Unlikely to share a language with the researcher*

2.1E.1h *Potentially in a student-teacher relationship with the researchers (e.g., a student subject pool)*

2.1E.1i *In any other dependent relationship with the researchers*

2.1E.1j *Likely to have difficulty in reading and/or comprehending any printed material distributed as part of the study*

2.1E.2 *Describe the measures that will be used to recruit, protect, and inform vulnerable participants*

2.1E.3 *If the research could induce any psychological stress or discomfort, state the nature of the risk and what measures will be taken to deal with such problems*

2.1E.4 *If the research requires any physically invasive or potentially physically harmful procedures, give details and outline procedures to be put in place to deal with potential problems*

2.1E.5 *If the research involves the investigation of any illegal behaviour, give details and outline procedures to be put in place to deal with potential problems*

2.1E.6 *If the research involves the investigation of any sensitive topics, give details and outline procedures to be put in place to deal with potential problems*

2.1E.7 *If your study has the capacity to unveil psychological or physical problems of which the participants may be unaware (for example, some rapid visual presentations might reveal visual field deficits), describe the assessments involved, the degrees of diagnostic sensitivity and specificity they confer, and the clinical conditions involved, and outline procedures to be put in place to deal with potential problems*

2.1E8 *If there is a real risk of disclosure of activities which should be reported to the authorities, a warning to this effect must be included in the Consent documents. Please provide the wording of this warning*

2.1E.9 *Will the true purpose of the research be concealed from the participants*

• *If the purpose will be concealed, explain what information will be concealed and why*

3.1.1 *State which professional organisation guidelines you are using*

3.1.1b *Other organisation Name*

3.1.1c *Other organisation URL*

3.1.2 *Will your study make use of subjects from the Volunteer Panel*

3.1.1 *State which professional organisation guidelines you are using*

3.1.1b *Other organisation Name*

3.1.1c *Other organisation URL*

3.1.1 *State which professional organisation guidelines you are using*

3.1.1b *Other organisation Name*

3.1.1c *Other organisation URL*

3.1.2 *Will your study make use of subjects from the Volunteer Panel*

3.1.3 *Are drugs, placebos or other substances to be administered to study participants, or will blood or tissue (e.g. saliva) samples be obtained from participants*

Submission signatories

Forename/Initials	Surname	E-mail	Date	Auth. User