

 **Tavistock and Portman Trust Research Ethics Committee (TREC)**

**APPLICATION FOR ETHICAL REVIEW OF STUDENT RESEARCH PROJECTS**

**This application should be submitted alongside copies of any supporting documentation which will be handed to participants, including a participant information sheet, consent form, self-completion survey or questionnaire.**

Where a form is submitted and sections are incomplete, the form will not be considered by TREC and will be returned to the applicant for completion.

For further guidance please contact Paru Jeram (academicquality@tavi-port.nhs.uk)

**FOR ALL APPLICANTS**

**If you already have ethical approval from another body (including HRA/IRAS) please submit the application form and outcome letters. You need only complete sections of the TREC form which are NOT covered in your existing approval**

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| Is your project considered as ‘research’ according to the HRA tool? (<http://www.hra-decisiontools.org.uk/research/index.html>) | Yes/No |
| Will your project involve participants who are under 18 or who are classed as vulnerable? (see section 7) | Yes/No |
| Will your project include data collection outside of the UK? | Yes/No |

**section a: Project Details**

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| **Project title** |  |
| **Proposed project start date** |  | **Anticipated project end date** |  |
| **Principal Investigator (normally your Research Supervisor):** |
| **Please note: TREC approval will only be given for the length of the project as stated above up to a maximum of 6 years. Projects exceeding these timeframes will need additional ethical approval** |
| **Has NHS or other approval been sought for this research including through submission via Research Application System (IRAS) or to the Health Research Authority (HRA)?**  | **YES (NRES approval)****YES (HRA approval)** **Other** **NO**  | **[ ]** **[ ]** **[ ]** **[ ]**  |
| **If you already have ethical approval from another body (including HRA/IRAS) please submit the application form and outcome letters.**  |

**section b: Applicant Details**

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| **Name of Researcher**  |  |
| **Programme of Study and Target Award** |  |
| **Email address** |  |
| **Contact telephone number** |  |

**section c: CONFLICTS OF INTEREST**

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| **Will any of the researchers or their institutions receive any other benefits or incentives for taking part in this research over and above their normal salary package or the costs of undertaking the research?** **YES [ ]  NO [ ]** If **YES**, please detail below: |
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| **Is there any further possibility for conflict of interest? YES [ ]  NO [ ]**  |
| **Are you proposing to conduct this work in a location where you work or have a placement?** **YES [ ]  NO [ ]** If **YES**, please detail below outline how you will avoid issues arising around colleagues being involved in this project: |
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| **Is your project being commissioned by and/or carried out on behalf of a body external to the Trust? (for example; commissioned by a local authority, school, care home, other NHS Trust or other organisation).**\*Please note that ‘external’ is defined as an organisation which is external to the Tavistock and Portman NHS Foundation Trust (Trust) | **YES [ ]  NO [ ]**  |
| If **YES**, please add details here: |
| **Will you be required to get further ethical approval after receiving TREC approval?**If **YES**, please supply details of the ethical approval bodies below AND include any letters of approval from the ethical approval bodies (letters received after receiving TREC approval should be submitted to complete your record): | **YES [ ]  NO [ ]**  |
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| If your project is being undertaken with one or more clinical services or organisations external to the Trust, please provide details of these:  |
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| If you still need to agree these arrangements or if you can only approach organisations after you have ethical approval, please identify the types of organisations (eg. schools or clinical services) you wish to approach: |
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| **Do you have approval from the organisations detailed above? (this includes R&D approval where relevant)**Please attach approval letters to this application. Any approval letters received after TREC approval has been granted MUST be submitted to be appended to your record | **YES [ ]  NO [ ]  NA [ ]**  |

**SECTION D: SIGNATURES AND DECLARATIONS**

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| **APPLICANT DECLARATION**I confirm that:* The information contained in this application is, to the best of my knowledge, correct and up to date.
* I have attempted to identify all risks related to the research.
* I acknowledge my obligations and commitment to upholding ethical principles and to keep my supervisor updated with the progress of my research
* I am aware that for cases of proven misconduct, it may result in formal disciplinary proceedings and/or the cancellation of the proposed research.
* I understand that if my project design, methodology or method of data collection changes I must seek an amendment to my ethical approvals as failure to do so, may result in a report of academic and/or research misconduct.
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| **Applicant (print name)** |  |
| **Signed** |  |
| **Date** |  |

**FOR RESEARCH DEGREE STUDENT APPLICANTS ONLY**

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| **Name of Supervisor/Principal Investigator** |  |

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| **Supervisor –*** Does the student have the necessary skills to carry out the research?

**YES [ ]  NO [ ]** * Is the participant information sheet, consent form and any other documentation appropriate?

**YES [ ]  NO [ ]** * Are the procedures for recruitment of participants and obtaining informed consent suitable and sufficient?

**YES [ ]  NO [ ]** * Where required, does the researcher have current Disclosure and Barring Service (DBS) clearance?

**YES [ ]  NO [ ]**  |
| **Signed** |  |
| **Date** |  |

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| **COURSE LEAD/RESEARCH LEAD**Does the proposed research as detailed herein have your support to proceed? YES [ ]  NO [ ]   |
| **Signed** |  |
| **Date** |  |

**SECTION E: Details of the proposed research**

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| 1. **Provide a brief description of the proposed research, including the requirements of participants. This must be in lay terms and free from technical or discipline specific terminology or jargon. If such terms are required, please ensure they are adequately explained (Do not exceed 500 words)**
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| 1. **Provide a statement on the aims and significance of the proposed research, including potential impact to knowledge and understanding in the field (where appropriate, indicate the associated hypothesis which will be tested). This should be a clear justification of the proposed research, why it should proceed and a statement on any anticipated benefits to the community. (Do not exceed 700 words)**
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| 1. **Provide an outline of the methodology for the proposed research, including proposed method of data collection, tasksassigned to participants of the research and the proposed method and duration of data analysis. If the proposed research makes use of pre-established and generally accepted techniques, please make this clear. (Do not exceed 500 words)**
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**SECTION F: Participant details**

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| 1. **Provide an explanation detailing how you will identify, approach and recruit the participants for the proposed research, including clarification on sample size and location. Please provide justification for the exclusion/inclusion criteria for this study (i.e. who will be allowed to / not allowed to participate) and explain briefly, in lay terms, why these criteria are in place. (Do not exceed 500 words)**
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| 1. **Please state the location(s) of the proposed research including the location of any interviews. Please provide a Risk Assessment if required. Consideration should be given to lone working, visiting private residences, conducting research outside working hours or any other non-standard arrangements.**

**If any data collection is to be done online, please identify the platforms to be used.** |
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| 1. **Will the participants be from any of the following groups?*(Tick as appropriate)***

[ ]  Students or Staff of the Trust or Partner delivering your programme.[ ]  Adults (over the age of 18 years with mental capacity to give consent to participate in the research).[ ]  Children or legal minors (anyone under the age of 16 years)1[ ]  Adults who are unconscious, severely ill or have a terminal illness.[ ]  Adults who may lose mental capacity to consent during the course of the research. [ ]  Adults in emergency situations.[ ]  Adults2 with mental illness - particularly those detained under the Mental Health Act (1983 & 2007).[ ]  Participants who may lack capacity to consent to participate in the research under the research requirements of the Mental Capacity Act (2005).[ ]  Prisoners, where ethical approval may be required from the National Offender Management Service (NOMS).[ ]  Young Offenders, where ethical approval may be required from the National Offender Management Service (NOMS).[ ]  Healthy volunteers (in high risk intervention studies).[ ]  Participants who may be considered to have a pre-existing and potentially dependent3 relationship with the investigator (e.g. those in care homes, students, colleagues, service-users, patients).[ ]  Other vulnerable groups (see Question 6).[ ]  Adults who are in custody, custodial care, or for whom a court has assumed responsibility.[ ]  Participants who are members of the Armed Forces.*1If the proposed research involves children or adults who meet the Police Act (1997) definition of vulnerability3, any researchers who will have contact with participants must have current Disclosure and Barring Service (DBS) clearance.* *2 ‘Adults with a learning or physical disability, a physical or mental illness, or a reduction in physical or mental capacity, and living in a care home or home for people with learning difficulties or receiving care in their own home, or receiving hospital or social care services.’ (Police Act, 1997)**3 Proposed research involving participants with whom the investigator or researcher(s) shares a dependent or unequal relationships (e.g. teacher/student, clinical therapist/service-user) may compromise the ability to give informed consent which is free from any form of pressure (real or implied) arising from this relationship. TREC recommends that, wherever practicable, investigators choose participants with whom they have no dependent relationship. Following due scrutiny, if the investigator is confident that the research involving participants in dependent relationships is vital and defensible, TREC will require additional information setting out the case and detailing how risks inherent in the dependent relationship will be managed. TREC will also need to be reassured that refusal to participate will not result in any discrimination or penalty.*  |
| 1. **Will the study involve participants who are vulnerable? YES [ ]  NO [ ]**

For the purposes of research, ‘vulnerable’ participants may be adults whose ability to protect their own interests are impaired or reduced in comparison to that of the broader population. Vulnerability may arise from:* the participant’s personal characteristics (e.g. mental or physical impairment)
* their social environment, context and/or disadvantage (e.g. socio-economic mobility, educational attainment, resources, substance dependence, displacement or homelessness).
* where prospective participants are at high risk of consenting under duress, or as a result of manipulation or coercion, they must also be considered as vulnerable
* children are automatically presumed to be vulnerable.
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| **7.1. If YES, what special arrangements are in place to protect vulnerable participants’ interests?** |
|  **If YES,** a Disclosure and Barring Service (DBS) check **within the last three years** is required.  Please provide details of the “clear disclosure”:

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| Date of disclosure: |
| Type of disclosure: |
| Organisation that requested disclosure: |
| DBS certificate number: |

 *(NOTE: information concerning activities which require DBS checks can be found via*  [*https://www.gov.uk/government/publications/dbs-check-eligible-positions-guidance*](https://www.gov.uk/government/publications/dbs-check-eligible-positions-guidance)*). Please* ***do not*** *include a copy of your DBS certificate with your application* |
| 1. **Do you propose to make any form of payment or incentive available to participants of the research? YES [ ]  NO [ ]**

If **YES**, please provide details taking into account that any payment or incentive should be representative of reasonable remuneration for participation and may not be of a value that could be coercive or exerting undue influence on potential participants’ decision to take part in the research. Wherever possible, remuneration in a monetary form should be avoided and substituted with vouchers, coupons or equivalent. Any payment made to research participants may have benefit or HMRC implications and participants should be alerted to this in the participant information sheet as they may wish to choose to decline payment. |
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| 1. **What special arrangements are in place for eliciting informed consent from participants who may not adequately understand verbal explanations or written information provided in English; where participants have special communication needs; where participants have limited literacy; or where children are involved in the research? (Do not exceed 200 words)**
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**SECTION F: RISK ASSESSMENT AND RISK MANAGEMENT**

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| 1. **Does the proposed research involve any of the following? *(Tick as appropriate)***

[ ]  use of a questionnaire, self-completion survey or data-collection instrument (attach copy)[ ]  use of emails or the internet as a means of data collection[ ]  use of written or computerised tests[ ]  interviews (attach interview questions)[ ]  diaries (attach diary record form)[ ]  participant observation[ ]  participant observation (in a non-public place) without their knowledge / covert research[ ]  audio-recording interviewees or events[ ]  video-recording interviewees or events[ ]  access to personal and/or sensitive data (i.e. student, patient, client or service-user data) without the participant’s informed consent for use of these data for research purposes[ ]  administration of any questions, tasks, investigations, procedures or stimuli which may be experienced by participants as physically or mentally painful, stressful or unpleasant during or after the research process[ ]  performance of any acts which might diminish the self-esteem of participants or cause them to experience discomfiture, regret or any other adverse emotional or psychological reaction[ ]  Themes around extremism or radicalisation[ ]  investigation of participants involved in illegal or illicit activities (e.g. use of illegal drugs) [ ]  procedures that involve the deception of participants[ ]  administration of any substance or agent[ ]  use of non-treatment of placebo control conditions[ ]  participation in a clinical trial[ ]  research undertaken at an off-campus location (risk assessment attached)[ ]  research overseas (please ensure Section G is complete)  |

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| 1. **Does the proposed research involve any specific or anticipated risks (e.g. physical, psychological, social, legal or economic)** **to participants that are greater than those encountered in everyday life?**

**YES [ ]  NO [ ]** If **YES**, please describe below including details of precautionary measures. |
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| 1. **Where the procedures involve potential hazards and/or discomfort or distress for participants, please state what previous experience the investigator or researcher(s) have had in conducting this type of research.**
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| 1. **Provide an explanation of any potential benefits to participants. Please ensure this is framed within the overall contribution of the proposed research to knowledge or practice. (Do not exceed 400 words)**

**NOTE:** Where the proposed research involves students , they should be assured that accepting the offer to participate or choosing to decline will have no impact on their assessments or learning experience. Similarly, it should be made clear to participants who are patients, service-users and/or receiving any form of treatment or medication that they are not invited to participate in the belief that participation in the research will result in some relief or improvement in their condition.  |
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| 1. **Provide an outline of any measures you have in place in the event of adverse or unexpected outcomes and the potential impact this may have on participants involved in the proposed research. (Do not exceed 300 words)**
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| 1. **Provide an outline of your debriefing, support and feedback protocol for participants involved in the proposed research. This should include, for example, where participants may feel the need to discuss thoughts or feelings brought about following their participation in the research. This may involve referral to an external support or counseling service, where participation in the research has caused specific issues for participants.**
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| 1. **Please provide the names and nature of any external support or counselling organisations that will be suggested to participants if participation in the research has potential to raise specific issues for participants.**
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| 1. **Where medical aftercare may be necessary, this should include details of the treatment available to participants. Debriefing may involve the disclosure of further information on the aims of the research, the participant’s performance and/or the results of the research. (Do not exceed 500 words)**
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**For Research undertaken outside the uk**

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| 1. **Does the proposed research involve travel outside of the UK? [ ]  YES [ ]  NO**

**If YES, please confirm:** **[ ]** I haveconsulted the Foreign and Commonwealth Office website for guidance/travel advice? <http://www.fco.gov.uk/en/travel-and-living-abroad/>  **[ ]** I have completed ta RISK Assessment covering all aspects of the project including consideration of the location of the data collection and risks to participants.All overseas project data collection will need approval from the Deputy Director of Education and Training or their nominee. Normally this will be done based on the information provided in this form. All projects approved through the TREC process will be indemnified by the Trust against claims made by third parties.If you have any queries regarding research outside the UK, please contact academicquality@tavi-port.nhs.uk: |
| Students are required to arrange their own travel and medical insurance to cover project work outside of the UK. Please indicate what insurance cover you have or will have in place. |
| 1. Please evidence how compliance with all local research ethics and research governance requirements have been assessed for the country(ies) in which the research is taking place. Please also clarify how the requirements will be met:
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**SECTION G: PARTICIPANT CONSENT AND WITHDRAWAL**

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| 1. **Have you attached a copy of your participant information sheet (this should be in *plain English*)? Where the research involves non-English speaking participants, please include translated materials.**

**YES [ ]  NO [ ]** If **NO**, please indicate what alternative arrangements are in place below: |
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| 1. **Have you attached a copy of your participant consent form (this should be in *plain English*)? Where the research involves non-English speaking participants, please include translated materials.**

**YES [ ]  NO [ ]** If **NO**, please indicate what alternative arrangements are in place below: |
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| 1. **The following is a participant information sheet checklist covering the various points that should be included in this document.**

[ ]  Clear identification of the Trust as the sponsor for the research, the project title, the Researcher and Principal Investigator (your Research Supervisor) and other researchers along with relevant contact details.[ ]  Details of what involvement in the proposed research will require (e.g., participation in interviews, completion of questionnaire, audio/video-recording of events), estimated time commitment and any risks involved.[ ]  A statement confirming that the research has received formal approval from TREC or other ethics body.[ ]  If the sample size is small, advice to participants that this may have implications for confidentiality / anonymity.[ ]  A clear statement that where participants are in a dependent relationship with any of the researchers that participation in the research will have no impact on assessment / treatment / service-use or support.[ ]  Assurance that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied.[ ]  Advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations.[ ]  A statement that the data generated in the course of the research will be retained in accordance with the [Trusts ’s Data Protection and handling Policies.](https://tavistockandportman.nhs.uk/about-us/governance/policies-and-procedures/): https://tavistockandportman.nhs.uk/about-us/governance/policies-and-procedures/[ ]  Advice that if participants have any concerns about the conduct of the investigator, researcher(s) or any other aspect of this research project, they should contact Head of Academic Registry (academicquality@tavi-port.nhs.uk)[ ]  Confirmation on any limitations in confidentiality where disclosure of imminent harm to self and/or others may occur. |
| 1. **The following is a consent form checklist covering the various points that should be included in this document.**

[ ]  Trust letterhead or logo.[ ]  Title of the project (with research degree projects this need not necessarily be the title of the thesis) and names of investigators.[ ]  Confirmation that the research project is part of a degree[ ]  Confirmation that involvement in the project is voluntary and that participants are free to withdraw at any time, or to withdraw any unprocessed data previously supplied.[ ]  Confirmation of particular requirements of participants, including for example whether interviews are to be audio-/video-recorded, whether anonymised quotes will be used in publications advice of legal limitations to data confidentiality.[ ]  If the sample size is small, confirmation that this may have implications for anonymity any other relevant information.[ ]  The proposed method of publication or dissemination of the research findings.[ ]  Details of any external contractors or partner institutions involved in the research.[ ]  Details of any funding bodies or research councils supporting the research.[ ]  Confirmation on any limitations in confidentiality where disclosure of imminent harm to self and/or others may occur. |

**SECTION H: CONFIDENTIALITY AND ANONYMITY**

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| 1. **Below is a checklist covering key points relating to the confidentiality and anonymity of participants. Please indicate where relevant to the proposed research.**

[ ]  Participants will be completely anonymised and their identity will not be known by the investigator or researcher(s) (i.e. the participants are part of an anonymous randomised sample and return responses with no form of personal identification)?[ ]  The responses are anonymised or are an anonymised sample (i.e. a permanent process of coding has been carried out whereby direct and indirect identifiers have been removed from data and replaced by a code, with no record retained of how the code relates to the identifiers).[ ]  The samples and data are de-identified (i.e. direct and indirect identifiers have been removed and replaced by a code. The investigator or researchers are able to link the code to the original identifiers and isolate the participant to whom the sample or data relates).[ ]  Participants have the option of being identified in a publication that will arise from the research.[ ]  Participants will be pseudo-anonymised in a publication that will arise from the research. (I.e. the researcher will endeavour to remove or alter details that would identify the participant.)[ ]  The proposed research will make use of personal sensitive data.[ ]  Participants consent to be identified in the study and subsequent dissemination of research findings and/or publication. |
| 1. **Participants must be made aware that the confidentiality of the information they provide is subject to legal limitations in data confidentiality (i.e. the data may be subject to a subpoena, a freedom of information request or mandated reporting by some professions). This only applies to named or de-identified data. If your participants are named or de-identified, please confirm that you will specifically state these limitations.**

**YES [ ]  NO [ ]** If **NO**, please indicate why this is the case below: |
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| **NOTE: WHERE THE PROPOSED RESEARCH INVOLVES A SMALL SAMPLE OR FOCUS GROUP, PARTICIPANTS SHOULD BE ADVISED THAT THERE WILL BE DISTINCT LIMITATIONS IN THE LEVEL OF ANONYMITY THEY CAN BE AFFORDED.**  |

**SECTION I: DATA ACCESS, SECURITY AND MANAGEMENT**

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| 1. **Will the Researcher/Principal Investigator be responsible for the security of all data collected in connection with the proposed research? YES [ ]  NO [ ]**

If **NO**, please indicate what alternative arrangements are in place below: |
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| 1. **In line with the 5th principle of the Data Protection Act (1998), which states that personal data shall not be kept for longer than is necessary for that purpose or those purposes for which it was collected; please state how long data will be retained for.**

 [ ]  1-2 years [ ]  3-5 years [ ]  6-10 years [ ]  10> years**NOTE: In line with** Research Councils UK (RCUK) guidance, doctoral project data should normally be stored for 10 years and Masters level data for up to 2 years  |
| 1. **Below is a checklist which relates to the management, storage and secure destruction of data for the purposes of the proposed research. Please indicate where relevant to your proposed arrangements.**

[ ]  Research data, codes and all identifying information to be kept in separate locked filing cabinets.[ ]  Research data will only be stored in the University of Essex OneDrive system and no other cloud storage location.[ ]  Access to computer files to be available to research team by password only.[ ]  Access to computer files to be available to individuals outside the research team by password only (See **23.1**).[ ]  Research data will be encrypted and transferred electronically within the UK.[ ]  Research data will be encrypted and transferred electronically outside of the UK. **NOTE:** Transfer of research data via third party commercial file sharing services, such as Google Docs and YouSendIt are not necessarily secure or permanent. These systems may also be located overseas and not covered by UK law. If the system is located outside the European Economic Area (EEA) or territories deemed to have sufficient standards of data protection, transfer may also breach the Data Protection Act (1998). Essex students also have access the ‘Box’ service for file transfer: [https://www.essex.ac.uk/student/it-services/box](https://protect-eu.mimecast.com/s/nlzlCQ0YPSkDXPmUxUb3M?domain=essex.ac.uk)[ ]  Use of personal addresses, postcodes, faxes, e-mails or telephone numbers.[ ]  Collection and storage of personal sensitive data (e.g. racial or ethnic origin, political or religious beliefs or physical or mental health or condition).[ ]  Use of personal data in the form of audio or video recordings.[ ]  Primary data gathered on encrypted mobile devices (i.e. laptops). **NOTE:** This should be transferred to secure University of Essex OneDrive at the first opportunity.[ ]  All electronic data will undergo secure disposal. **NOTE**: For hard drives and magnetic storage devices (HDD or SSD), deleting files does not permanently erase the data on most systems, but only deletes the reference to the file. Files can be restored when deleted in this way. Research files must be overwritten to ensure they are completely irretrievable. Software is available for the secure erasing of files from hard drives which meet recognised standards to securely scramble sensitive data. Examples of this software are BC Wipe, Wipe File, DeleteOnClick and Eraser for Windows platforms. Mac users can use the standard ‘secure empty trash’ option; an alternative is Permanent eraser software.[ ]  All hardcopy data will undergo secure disposal.**NOTE:** For shredding research data stored in hardcopy (i.e. paper), adopting DIN 3 ensures files are cut into 2mm strips or confetti like cross-cut particles of 4x40mm. The UK government requires a minimum standard of DIN 4 for its material, which ensures cross cut particles of at least 2x15mm. |
| 1. **Please provide details of individuals outside the research team who will be given password protected access to encrypted data for the proposed research.**
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| 1. **Please provide details on the regions and territories where research data will be electronically transferred that are external to the UK:**
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**SECTION J: Publication and dissemination of research FINDINGS**

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| 1. **How will the results of the research be reported and disseminated? *(Select all that apply)***

[ ]  Peer reviewed journal[ ]  Non-peer reviewed journal[ ]  Peer reviewed books[ ]  Publication in media, social media or website (including Podcasts and online videos)[ ]  Conference presentation[ ]  Internal report[ ]  Promotional report and materials[ ]  Reports compiled for or on behalf of external organisations[ ]  Dissertation/Thesis[ ]  Other publication[ ]  Written feedback to research participants[ ]  Presentation to participants or relevant community groups[ ]  Other (Please specify below) |

**SECTION K: Other ethical issues**

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| 1. **Are there any other ethical issues that have not been addressed which you would wish to bring to the attention of Tavistock Research Ethics Committee (TREC)?**
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**SECTION L: CHECKLIST FOR ATTACHED DOCUMENTS**

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| 1. Please check that the following documents are attached to your application.

[ ]  Letters of approval from any external ethical approval bodies (where relevant)[ ]  Recruitment advertisement[ ]  Participant information sheets (including easy-read where relevant)[ ]  Consent forms (including easy-read where relevant)[ ]  Assent form for children (where relevant)[ ]  Letters of approval from locations for data collection[ ]  Questionnaire[ ]  Interview Schedule or topic guide[ ]  Risk Assessment (where applicable)[ ]  Overseas travel approval (where applicable) |
| 1. **Where it is not possible to attach the above materials, please provide an explanation below.**
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