A checklist should be completed for every research project that involves generating new data with human participants in order to identify whether a full application for ethics approval needs to be submitted.

The chief investigator or, where the chief investigator is a student, the supervisor, is responsible for exercising appropriate professional judgement in this review. Sections I-V below must be completed before potential participants are approached to take part in any research.

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| **Section II: Student details** | | |
| Student name: |  | |
| Email: | |  |

***Instructions for Filling in this Form***

* If any questions in Section V are answered YES, please fill in Sections VI-IX of the form below before submitting it for review to REAG officer t.g.aistrope@kent.ac.ukalong with any supporting documentation such as **participant information sheets and consent forms.**
* Please note that as chief investigator it is your responsibility to follow, and to ensure that all researchers involved with your project, follow accepted ethical practice and appropriate professional guidelines in the conduct of your study. You must take all reasonable steps to protect the dignity, rights, safety and well-being of participants. This includes providing participants with appropriate information sheets, ensuring informed consent and ensuring confidentiality in the storage and use of data. In signing this form you are confirming this. **Please note that any significant change in the question, design or conduct over the course of the research should be notified to the REAG officer and may require a new application for ethics approval.**

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| **Section V: Research Checklist** |

Please answer all questions by ticking the appropriate box. **Please note, if the answer to any questions in this section is *YES* you MUST also fill in Sections VI-IX of the form below.**

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| 1. **Research that may need to be reviewed by an NHS Research Ethics Committee, the Social Care Research Ethics Committee (SCREC) or other external ethics committee (if *yes*, please give brief details as an annex)** | **YES** | **NO** |
| Will the study involve recruitment of patients through the NHS or the use of NHS patient data or samples? |  |  |
| Will the study involve the collection of tissue samples (including blood, saliva, urine, etc.) or other biological samples from participants, or the use of existing samples? |  |  |
| Will the study involve participants, or their data, from adult social care, including home care, or residents from a residential or nursing care home? |  |  |
| Will the study involve research participants identified because of their status as relatives or carers of past or present users of these services? |  |  |
| Does the study involve participants aged 16 or over who are unable to give informed consent (e.g. people with learning disabilities or dementia)? |  |  |
| Is the research a social care study funded by the Department of Health? |  |  |
| Is the research a health-related study involving prisoners? |  |  |
| Is the research a clinical investigation of a non-CE Marked medical device, or a medical device which has been modified or is being used outside its CE Mark intended purpose, conducted by or with the support of the manufacturer or another commercial company to provide data for CE marking purposes? (a CE mark signifies compliance with European safety standards) |  |  |
| Is the research a clinical trial of an investigational medicinal product or a medical device? |  |  |

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| 1. **Research that may need full review** | **YES** | **NO** |
| Does the research involve other vulnerable groups: children; those with cognitive impairment; or those in unequal relationships, e.g. your own students? |  |  |
| Does the project involve the collection of material that could be considered of a sensitive, personal, biographical, medical, psychological, social or physiological nature. |  |  |
| Will the study require the cooperation of a gatekeeper for initial access to the groups or individuals to be recruited (e.g. headmaster at a School; group leader of a self-help group)? |  |  |
| 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?) |  |  |
| Will the study involve discussion of sensitive topics (e.g. sexual activity; drug use; criminal activity)? |  |  |
| Are drugs, placebos or other substances (e.g. food substances, vitamins) to be administered to the study participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind? |  |  |
| Is pain or more than mild discomfort likely to result from the study? |  |  |
| Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life? |  |  |
| Will the study involve prolonged or repetitive testing? |  |  |
| Will the research involve administrative or secure data that requires permission from the appropriate authorities before use? |  |  |
| Is there a possibility that the safety of the researcher may be in question (e.g. international research; locally employed research assistants)? |  |  |
| Does the research involve participants carrying out any of the research activities themselves (i.e. acting as researchers as opposed to just being participants)? |  |  |
| Will the research take place outside the UK? |  |  |
| Will the outcome of the research allow respondents to be identified either directly or indirectly (e.g. through aggregating separate data sources gathered from the internet)? |  |  |
| Will research involve the sharing of data or confidential information beyond the initial consent given? |  |  |
| Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants? |  |  |
| Will the proposed findings be controversial or are there any conflicts of interest? |  |  |

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| 1. **Security Sensitive Material** | **YES** | **NO** |
| Does your research involve access to or use of material covered by the Terrorism Act?  (The Terrorism Act (2006) outlaws the dissemination of records, statements and other documents that can be interpreted as promoting and endorsing terrorist acts. By answering ‘yes’ you are registering your legitimate use of this material with the Research Ethics Advisory Group. In the event of a police investigation, this registration will help you to demonstrate that your use of this material is legitimate and lawful). |  |  |

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| 1. **Prevent Agenda** | **YES** | **NO** |
| Does the research have the potential to radicalise people who are vulnerable to supporting terrorism or becoming terrorists themselves? | ☐ | ☐ |

**If the answer to any questions in the check list above is ‘yes’, please complete the full application form including the sections below**

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| **Section VI: Purpose of Project** |

Please provide a brief outline (one/two paragraphs) of the project written in lay-person’s language, assuming that the reader is unfamiliar with the subject.

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| **Section VII: Project details** |

a) Location of the research:

b) Brief description of participants, including location and number

c) Brief description of controls and number

d) Brief account of how the Data Protection Act will be complied with

(for an outline of the main issues raised by the Act, see Research Services, <http://www.kent.ac.uk/researchservices/res-govern-frmewrk/legislation.html> )

e) Payment of participants (if any):

g) Source of funding (if any):

h) Brief account of methodology/techniques (a summarised account of measures to be used should be included as should examples of any questionnaires etc):

i) Brief account of how participants will be selected and any issues that arise relating to the selection of participants

j) Does your research involve access to or use of security-sensitive material? If yes, please note that the Terrorism Act (2006) outlaws the dissemination of records, statements and other documents that can be interpreted as promoting and endorsing terrorist acts. By answering ‘yes’ you are registering your legitimate use of this material with the Research Ethics Advisory Group.  In the event of a police investigation this registration will help you to demonstrate that your use of this material is legitimate and lawful. Please explain why you need access to security-sensitive and how you intend to use it.

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| **Section VIII: Risk, Harm and Benefit** |

a) Any risks to the participants (including the researcher(s)): this might include all forms of harm, e.g. physical or psychological. Particular attention should be paid to the potential to cause distress and embarrassment. Please discuss measures to be taken where necessary to ensure the welfare and safety of participants.

b) Issues relating to confidentiality during the project and in subsequent data analysis, presentation and publication.

c) Anticipated difficulties, particularly those relating to power imbalances between researcher and participants, e.g. staff/students or where dependant relationships are involved.

d) Details of how the project meets the four main ethical principles of research i.e. non-maleficence (not causing harm), beneficence (doing good), autonomy (treating people with respect and enabling them to make their own choices), and justice (who will be advantaged and disadvantaged by the research).

e) Where appropriate, details of how the research will take account of cultural issues, including some understanding of the need to provide appropriate interpreters, etc.

f) The rationale for the decision to pay, or not to pay, participants and the likely impact on participation. It should be noted that all incentives, whether monetary or otherwise may represent an unethical inducement to participation.

g) Issues relating to information to be provided to participants in advance of, or during the research. Issues relating to the intended feedback, or otherwise of research results to participants.

h) Information about other review procedures to which the research project has already been subjected, including management approval where staff are involved as subjects. Is further or alternative ethical review required?

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| **Section IX: Consent** |

a) Details of how it is intended that informed consent be obtained from the participants. Depending on the nature of the research, this can involve the production of a written information sheet that includes a mechanism for the participant to evidence that their consent has been obtained. Copies of any relevant documentation should be included with this application.

b) Procedures for gaining permission from participants who are unable to give informed consent (materials should be attached).

c) A special case has to be made for any cases where it is not possible to obtain consent.