**St. George’s School of Health and Medical Sciences**

**Research Ethics Committee**

**Joint Research and Enterprise Services**

**Ground Floor, Jenner Wing**

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| **Application form** |

\*\*\*\*\*\*\*\*\*\*DELETE EVERYTHING BETWEEN THE ASTERISKS BEFORE SUBMITTING\*\*\*\*\*\*\*\*\*\*

**Instructions for Completion**

This guidance is designed to help you write the protocol suitable for the JRES review when applying for St George’s Ethics Committee favourable opinion.

We colour coded the template to provide you with the following:

1. Text in red is for instructions only and needs to be deleted when the information required for that particular section of the protocol is completed. Therefore, please ensure any entry you make on to this form is in black.
2. **Text in black** should not be deleted as it is integral to the application form and ensures you have included all relevant information about your project. **Any existing black text should not be amended or deleted.**
3. **Text in grey** indicates an interactive field.

It is important to keep all headings to enable full review of your project and to ensure that you have addressed all issues. You may add extra subheadings if you find this useful. It is accepted that not all headings are appropriate for all research, and some may need to be removed. Where some protocol headings are not applicable to your study please write ‘Not applicable’ and leave the heading.

Please ensure that you add the study title, version number and date to the footer of the document.

DELETE ALL RED TEXT BEFORE SUBMITTING

IF YOU DO NOT DO SO YOUR APPLICATION WILL BE RETURNED TO YOU AND YOU WILL BE ASKED TO AMEND IT ACCORDINGLY

PLEASE DELETE THE “INSTRUCTIONS FOR COMPLETION” SECTION BEFORE SUBMITTING YOUR FORM

\*\*\*\*\*\*\*\*\*\*DELETE EVERYTHING BETWEEN THE ASTERISKS BEFORE SUBMITTING\*\*\*\*\*\*\*\*\*\*

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| --- | --- | --- | --- |
| **Full study title:** |  | | |
| **Short title:** |  | | |
| **REC Reference number:** | xxxx.2020 | | |
| **Type:** | Please select |  | |
| **Study Design:** | Please select |  | |
| **Planned sample size** |  | | |
| **Study Duration** | **Anticipated start date:** | | **Anticipated end date:** |
| Click here to enter a date | | Click here to enter a date |

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| Section 1: Study Summary |

## 1 Personnel

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| --- | --- |
| **Chief Investigator/Academic Supervisor (delete as appropriate)** | |
| **Name** |  |
| **Position** |  |
| **Affiliation** | Choose an item. |
| **Work Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |
| **Summary of experience relevant to this project** |  |

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| --- | --- |
| **Student *(delete if not applicable)*** | |
| **Name** |  |
| **Course/Degree title** |  |
| **Email address** |  |
| **Summary of experience relevant to this project (if applicable)** |  |

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| --- | --- |
| **Clinical Supervisor *(delete if not applicable)*** | |
| **Name** |  |
| **Position** |  |
| **Work Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |
| **Summary of experience relevant to this project** |  |

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| **Other investigators/collaborators *(delete if not applicable; add additional rows if necessary)*** | |
| **Name** |  |
| **Position** |  |
| **Work Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |
| **Summary of experience relevant to this project** |  |
| **Project manager *(delete if not applicable)*** | |
| **Name** |  |
| **Position title** |  |
| **Work Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |
| **Summary of experience relevant to this project (if applicable)** |  |

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| **Statistician *(delete if not applicable)*** | |
| **Name** |  |
| **Position** |  |
| **Work Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |
| **Summary of experience relevant to this project** |  |

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| Section 2: Study Protocol |

## 2a) Background and Rationale

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| Summary of the project |
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| Background |
| Provide any relevant background information and a rationale to support the research area, the area to be studied and study population. This should also include a summary of why you selected this area to conduct your research and the potential benefit or interest of the study.  This may include findings from clinical trials, non-clinical studies or previous clinical experience and cross references should be used. A reference list should be included at the end of the protocol. |

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| Research Question |
| Please state your research question and main study aim and state the specific objectives you are trying to achieve with this study.  Aim  Secondary Aim(s)/Objectives |

## 2b) Methods

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| Study design |
| Overall design, intervention plan and rationale  *This section of the protocol should include a detailed description of the type/design of the study to be conducted. Include information on the overall design, any intervention plan and the rationale for it.*  Location  *It should include where the study is going to be conducted, i.e. the department/trust/trust division/SGUL institute in which your study will be conducted. Please state if your research is going to be undertaken abroad, and if so what local ethical approval/governance procedures you have followed.*  *Describe any online tools you are using, or confirm that COVID-safe measures are in place and will be adhered to, if it is a face-to-face meeting*  Procedures  *What personal information/data/tissue will be taken?* *How many visits/tasks will they have to make? How long will the participant be involved in the study?*  *Provide details of all study related procedures, including obtaining informed consent, any assessments or testing of participants (including administration of questionnaires or interviews and baseline assessments). Include how this may differ between different groups of participants (e.g. treatment and control groups, sham treatments etc.).*    *Will any audio/video recordings be taken, transcript availability (recordings are optional or required for participation). Need to incorporate in consent form.*  *Please note that MS Teams records a video and audio recording at the same time.*  *Is both a video and audio recording essential for participants to be able to take a part in your study? If video recording is optional, you can indicate this in the study protocol, PIS andConsent Form. If the participants can opt out they can switch the camera off during the interview.*  *Please indicate if you will use any additional recording device.*    *Will they be contacted for future research? What type of future research? Any future research must be ethically-approved. Where it will be held and who will have access to it? How can the participants withdraw from it? Please add the same information to the PIS and Consent Form too.*  *Benefits of the study*  Patient/Participants involvement and peer review |

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| Study population |
| This section should state your target population (the maximum number of participants you could potentially recruit, fitting your aims, and reasoning for the chosen population). How did you measure the potential participant`s number?  You should also define the sampling technique used (i.e. random sampling, convenience sampling, etc) and an estimation of the sample size (predicted or set) should also be described here.  Describe whether you will collect data from a standardised/validated tool (e.g. McGill pain score) or involves a procedure (in which case full details should be supplied). Inclusion criteria This section should contain details of age, sex, etc. under which a participant is eligible to participate/be included in the study. This also includes, for example, volunteers and any “control” groups. Each such “group” should be defined separately. Informed consent to participate (preferably written and witnessed) must be stated as an inclusion criterion.  A simple list format or bullet points is the preferred style. Exclusion criteria Any criteria which would exclude a potential participant from participating in your study should be listed here. Participant recruitment process If you are doing retrospective studies or studies that do not involve recruiting participants, please delete this subsection.  If you are doing interventional, prospective or studies that in general involve recruiting participants, please complete this subsection. Describe recruitment methods such as the use of adverts, websites and the involvement of different centres/sites. |
| Informed consent If you are doing retrospective studies or studies that do not involve recruiting participants, please delete this sub-section.  If you are doing interventional, prospective or studies that involve recruiting participants, please insert procedures specifying:   1. Who will take informed consent? It must be clearly stated in this section to ensure that the main REC approves it. 2. How and when will it be taken? Base this on the information provided in the PIS. 3. How long will participants be given to make a decision on whether or not to take part in the study? 4. What will happen to consent forms after they are signed? Where will they be stored?   Please note for questionnaire studies a separate signed consent form may not be necessary. The completion and return of the completed questionnaire would be accepted as implied consent. You would need to ensure that the information accompanying the questionnaire fully explained the purpose of the research and what the data collected would be used for.  Informed consent from the participant, legally authorised representative or the parents/guardians/person with legal responsibility for children must be obtained following explanation of the aims, methods, benefits and potential hazards of the study and before any study specific procedures are performed.  *Please note the recognised electronic signatures for the online Consent forms according to the HRA guidance:*  *“Simple electronic signatures – examples are a stylus or finger drawn signature, a typed name, a tick box and declaration, a unique representation of characters and a fingerprint scan.* Withdrawal of participants and stopping criteria If you are doing retrospective studies or studies that do not involve recruiting participants, please delete this subsection.  If you are doing interventional, prospective or studies that involve recruiting participants, please state how participants can withdraw from the study and under what circumstances investigators/members of the research team may choose to withdraw an individual from the study. Explain what will happen to data already collected from a participant should they wish to withdraw or if they lose capacity.  *If vulnerable persons are to be used in the study, please give separate specific information on how you will ensure informed consent. If participants whose first language is not English are to be recruited, please state clearly how the details of the study will be explained and the informed consent process will be handled.* |

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| Data Management |
| Data collection techniques In this section you should specify where you are going to collect your data from (i.e. clinical records, reports, follow-up printouts, questionnaires etc.) if applicable and how you are going to collect your data. If there are going to be multiple data collection points, it is easiest to list the details per time-point. Describe the type of data (personal, sensitive) that you collect and procedures for data collection and recording. Data collection tool If you will be using a data collection tool, e.g. to record observations, please include this in your application and describe it here. Describe how/what method you will be employing to answer the research question and satisfy the study aims. In addition, please describe methods used to maximise completeness of data (e.g. telephoning subjects who have not returned postal questionnaires). Quality Control should be applied at each stage of data handling to ensure that all data are reliable and have been processed correctly. Confidentiality – Data storage *Explain how you will maintain the confidentiality of any data collected. It is not sufficient to simply state “the data will be treated confidentially” – you will need to explain how you will do this in terms of anonymisation, physical and electronic security.*  Explain how you will handle and store data safely and in accordance with data protection guidelines. In general, you should specify where, how you are going to keep/store your data (e.g. Excel database, university network) during the project and after the project ends and how you are going to protect your data (anonymisation, data security etc.). Incidental findings This section is aimed at establishing the capacity for inadvertent/incidental data that have potential relevance for participants or their families and the feedback mechanisms used.  Data Analyses Strategies  In this section you should specify the statistics software you will be using, and the general statistical tests you will be using for each type of data.  Plans for statistical analyses should be included in this section and should typically include a summary of the measures to be reported and method of analysis (justified with consideration of [assumptions](http://www.sgul.ac.uk/depts/chs/chs_research/stat_guide/methods.cfm#assump) of the method, structure of the data (e.g. [unpaired, paired](http://www.sgul.ac.uk/depts/chs/chs_research/stat_guide/methods.cfm#paired), [hierarchical](http://www.sgul.ac.uk/depts/chs/chs_research/stat_guide/methods.cfm#hier)) etc.). Details on what form the analysis will take (e.g. for continuous, categorical, and/or ordinal variables) and how it will be reported (e.g. means, standard deviations, medians, proportions) must be expanded on in this section.  Plans for handling multiple comparisons, missing data, non-compliance, spurious data and withdrawals in analysis must also be addressed here. |

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| Ethical Considerations |
| In this section you should address any ethical considerations with your study. Consider issues and risks associated with participants, researchers themselves or any other groups, such as St. George’s, University of London or your funders. Explain how you will reduce or mitigate these. It is important to also include how you will deal with any incidental findings.  Please add any available supporting, counselling services to this section and PIS as well. |

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| Dissemination |
| Please state what you are planning to do with your research findings/data. If your research is connected to SGUL students or staff please indicate the route of the feedback to SGUL. |

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| References |
| References should be completed using the Harvard, Vancouver or APA referencing style. |

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| Section 3: Risk Assessment |

| 1. **Identified Risks** | 1. **Likelihood** | 1. **Potential Impact/**   **Outcome** | 1. **Potential Severity of Outcome** | 1. **Risk Management/Mitigating Factors** | |
| --- | --- | --- | --- | --- | --- |
| *Identify risks/hazards present* | *Identify how likely the event is i.e.*  *Very likely/ Likely/ Possible/ Unlikely* | *Who might be harmed and how?*  *Ensure you have considered the research team, participants and anyone not directly involved in the research.* | *Classify the severity of outcomes identified in 3.*  *i.e. High/ Medium/ Low* | *Evaluate the risks and decide on the precautions.* | *Standard Operating Procedures\*/ risk assessments*  *Enter Ref no/ title/ expiry date* |
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*The following is an example for research involving one-to-one interviews with adults in participants’ homes. The interview may touch on issues that might be sensitive for some participants.*

| ***Risk Assessment for Study: Example*** | | | | | |
| --- | --- | --- | --- | --- | --- |
| ***Version: 1*** | ***Date: 21 Mar 2020*** | | | | |
| 1. ***Identified Risks*** | 1. ***Likelihood*** | 1. ***Potential Impact/Outcome*** | 1. ***Potential Severity of Outcome*** | 1. ***Risk Management/Mitigating Factors*** | |
| *Identify risks/hazards present* | *Identify how likely the event is i.e.*  *Very likely/ Likely/ Possible/ Unlikely* | *Who might be harmed and how?*  *Ensure you have considered the research team, participants and anyone not directly involved in the research.* | *Classify the severity of outcomes identified in 3.*  *i.e. High/ Medium/ Low* | *Evaluate the risks and decide on the precautions.* | *Standard Operating Procedures/ risk assessments*  *Enter Ref no/ title/ expiry date* |
| *Risk of verbal or physical attack when interviewing participant alone* | *Unlikely* | *Researcher:*   * *Physical injury* * *Psychological harm* | *Medium* | * *Participants referred by colleagues* * *Researcher to follow local lone working policy* | *NA* |
| *Discussion of a sensitive topic in an interview has potential to cause participant distress* | *Possible* | *Participant:*   * *Psychological stress*   *Researcher:*   * *Anxiety about dealing with complex situation* | *Medium* | * *Questions direct participants to talk about procedures rather than personal experiences* * *Offer to cease interview if participant becomes distressed* * *Signpost participant to external/internal support services in Participant Information Sheet and Debriefing statement* | *NA* |
| *Disclosure of information that might need reporting to authorities* | *Possible* | *Response may be required from service providers* | *High* | * *Researcher refer disclosure to the appropriate party* * *Ensure all verbal and written information about research indicates possible researcher response to disclosure* | *NA* |
| *Risk of data loss* | *Unlikely* | *Participant:*   * *Contribution wasted*   *Researcher:*   * *Stress due to imperilment of research* | *Medium* | * *Interviews will be recorded on encrypted audio device* * *Recordings will be securely stored until transcription and then destroyed* * *Anonymised transcripts will be stored in a secure location on University servers and transferred to an external archive* |  |
| *Risk of breaching participant confidentiality* | *Unlikely* | *Participant/ researcher:*   * *Anxiety due to potential for confidential information to be in the public domain* * *Reputational risk* | *Medium* | * *Interviews will be conducted in privacy of participants home to avoid conversations being overheard* * *Measures to secure data as described under risk of data loss* | *NA* |
| *Risk of identifying participants* | *Unlikely* | *Participant/ researcher:*   * *Anxiety due to role in the research being in the public domain* * *Reputational risk* | *Medium* | * *Consent forms will be stored in locked draws in secure rooms* * *Interview transcripts will be anonymised and stored securely* * *Results will be reported without direct (e.g. names) and indirect identifiers (e.g. workplace, job title)* |  |

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| Section 4: Ethics, Governance and Regulatory Compliance |

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| Ethics and Research Governance requirements |
| Please provide a statement of compliance. If your study is going through HRA approval or R&D approval at another NHS site, please provide details here.  Please include approvals from organisations abroad where applicable.  If this section is not applicable to your study, please insert “not required”. |

|  |
| --- |
| Finance and Funding |
| Insert information on any funding applied for or already awarded to undertake the study. Put “not applicable” if study not funded. |

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| Insurance |
| Insert information on any insurance applied for or received for the study. Financial provision for insurance should normally be made during the grant application process. |

|  |
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| Publication Policy and Intellectual Property |
| Insert here any details about if and where you will publish the results, including any plans for public dissemination and informing the participants of the results. |

|  |  |  |
| --- | --- | --- |
| Previous Ethics opinion | | |
|  |  | **Provide details** |
| Has any part of this research received prior ethics opinion from another Committee? | Yes  No | *Give name of committee and date* |
| Has any part of this research/proposal been rejected by another Committee? | Yes  No | *Give name of committee, date etc.* |

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| Section 5: Declaration |

## 5a) Statement of Compliance

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| --- | --- | --- | --- |
| The Principal Investigator/Academic Supervisor/student/clinical supervisor/all investigators/collaborators *(please delete/add as appropriate)* have discussed this protocol version and certify that all information provided in this document is accurate.  The investigators agree to perform the investigations and to abide by this protocol except where departures from it are mutually agreed in writing. No deviation from the protocol will be implemented without the prior review and agreement of St. George’s Research Ethics Committee (SGREC) except where it may be necessary to eliminate an immediate hazard to a research participant. In such case, the deviation will be reported to the SGREC within 7 days. The SGREC will be informed if there are any changes made to the research protocol, personnel or other study documents via an amendment submitted to the SGREC.  The study will be conducted in compliance with the approved protocol, the UK Data Protection Act (2018), the UK Policy Framework for Health and Social Care Research 2017, and any other applicable regulatory requirement(s), as appropriate. The study shall comply with all relevant laws of the EU if directly applicable or of direct effect and all relevant laws and statutes of the UK country in which the study site is located, including but not limited to The Human Rights Act 2018, the Data Protection Act 2018 and the World Medical Association Declaration of Helsinki entitled “Ethical Principles for Medical Research Involving Human Subjects” (2013 version). If the research site(s) is/are located outside of the UK, the study will be conducted in compliance with all local ethical, regulatory and legal requirements for the research to be conducted in that country or countries.  Furthermore, the study team agrees to provide an Annual Progress Report of the study until the end of the study and notify the SGREC of the end or early termination of the research project. The study team will assist the SGREC in any continuing review of the project deemed necessary by the SGREC, and the study team will otherwise reapply for ethical favourable opinion after 5 years. | | | |
| Chief Investigator/  Academic Supervisor  *(delete as appropriate)* | *Insert Name*  *Insert Position*  *Employer (e.g. SGUL/SGHT etc) (delete as appropriate)* | *(CI/supervisor signature – delete before printing and signing. Electronic signatures are accepted)* | |
|  |  | Date: | Click here to enter a date. |

|  |  |
| --- | --- |
| Please tick if you would be willing to attend the SGREC meeting in order to discuss your application where full Committee review is required. Attendance is not mandatory but may slow the process of your application if the SGREC needs to field queries to you after the meeting |  |