*Instructions for Use: Aim to complete every section: if a section is not pertinent to your study it can be amended/deleted, extra sections may be added if necessary.* ***Please delete all blue italics before submission.***

**LOGO** *University of Surrey Logo and funder if applicable*

**FULL/LONG TITLE OF THE STUDY**

*Aim: To identify the study to enable retrieval from literature or internet searches. It should be immediately evident what the study is investigating and on whom to allow rapid judgment of relevance.*

**SHORT STUDY TITLE / ACRONYM**

*Aim: To provide a summary of the long title. It is usually the title used on information sheets and consent forms for research participants or others giving consent or assent on their behalf.*

*The short title should be:*

* *Sufficiently detailed to make clear to participants what the research is about in simple lay language*
* *If acronyms are used the full title should explain them. The proposed acronym should not drive the long title*
* *Ideally unique as to enable easy search from internet searches*

**PROTOCOL VERSION NUMBER AND DATE**

*Aim: To track changes to the document for study conduct, review, and oversight so it is clear which is the most recent document.*

*Version control:*

* *All draft versions should be numbered 0.1, 0.2 etc.*
* *The final version for submission should be numbered 1.0*

LIST of CONTENTS (optional)

Confidentiality Statement

The Information contained in this document is the property of the University of Surrey and is provided to you in confidence as an investigator, potential investigator, or consultant for review by you, your staff and applicable regulators. It is understood that this information will not be disclosed to others without authorisation from the University of Surrey except to the extent necessary to obtain written consent from those persons who will take part in the study.

**STUDY SUMMARY (Optional)**

*Aim: Useful to include for quick reference. Complete information and, if required, add additional rows.*

|  |  |
| --- | --- |
| Study Title |  |
| Internal ref. no. (or short title) |  |
| Planned Size of Sample (if applicable) |  |
| Planned Study Period |  |

**FUNDING AND SUPPORT IN KIND (Optional)**

*Aim: to make clear the funding and or services in kind received.*

|  |  |
| --- | --- |
| **FUNDER(S)**(Names and contact details of ALL organisations providing funding and/or support in kind for this study) | **FINANCIAL AND NON FINANCIAL SUPPORT GIVEN** |
|  |  |
|  |  |
|  |  |

**INVESTIGATORS**

|  |  |  |
| --- | --- | --- |
| **NAME** | **Position** | **Signature (optional)** |
|  |  |  |
|  |  |  |
|  |  |  |

**STUDY PROTOCOL**

### Abstract

*Aim: To provide a brief summary of the study, in simple terms a non-specialist can understand*

### Background or rationale of the project

*Aim: To provide the reason why you are conducting the study, highlighting previous work gap and the need for the research. Please keep this section informative and concise, and do not exceed 1 page.*

1. **Patient/Participant involvement**

*Aim: To describe in what aspects of the protocol design have potential participants, patients, service users, and/or their carers, or members of the public been involved. Please DO NOT describe study participants, recruitment methods, interventions or procedures, rather it is to indicate how patients, potential participants and public stakeholders have been consulted and contributed to the design and delivery of the research prior to commencing the study.*

*If there has been no pre-study PPI, it is acceptable to indicate this - it is unlikely to directly affect the UEC review outcome.*

*Further information can be found on the Health Research Authority website:*[*https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/*](https://eur02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hra.nhs.uk%2Fplanning-and-improving-research%2Fbest-practice%2Fpublic-involvement%2F&data=05%7C01%7Cmilo.thomson%40surrey.ac.uk%7C5f49bef6a29948bc7aef08da845e55ef%7C6b902693107440aa9e21d89446a2ebb5%7C0%7C0%7C637967837984521406%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=t1dUMt0qPh2R5FONWLPhk0xbWV02hi78vcdKVPg2UYs%3D&reserved=0)

### Aims and objectives

*Aim: To highlight the aims of the study, ‘research question’ and what the outcomes might be.*

### Benefits of the study

*Aim: to highlight the potential impact of your research either directly on the participants, the participant group, to further knowledge or change policy.*

1. **Recruitment Methods**

*Aim: to describe all the recruitment methods you plan to use and provide details of any prior approvals you will need to gain. Also use this to highlight your inclusion/exclusion criteria.*

### Adverse Publicity

*Aim: to highlight any potential risks or backlash the study may encounter once it’s advertised on public channels, especially via social media which can escalate out of your control. Consider whether any part of your study may be misinterpreted and how you would mitigate such a risk. Adverse publicity should be considered at both at the recruitment stage and also for any publishing.*

### Informed Consent and Withdrawal of Consent

### *Aim: Describe the consent process and how consent will be recorded. Also to highlight what will happen to participants’ data should they withdraw. Including inclusion/exclusion criteria*

### Experimental design, data collection and methods (including data analysis)

*Aim: To describe what you will be expecting from your participants, how you will collect your data and how you will analyse the data. If you have used calculations to determine sample size, it should be described here. Including a schedule of events if applicable.*

e.g. Table 1. Schedule of Events

|  |  |
| --- | --- |
| **Procedures** | **Visits (insert visit numbers as appropriate)** |
| **Screening** | **Baseline** | **Week 4** | **Week 8** | **6 Months** |
| Informed consent | x |  |  |  |  |
| Demographics |  | x |  |  |  |
| history |  | x |  |  |  |
| Intervention |  | x | x | x |  |
| Interview |  |  |  |  | x |

### 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* |
| *Eg., Data loss* |  |  |  |  |  |
| *Eg.,Data breach* |  |  |  |  |  |
| *Eg., Adverse publicity* |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[**Click Here for Risk Assessment – Worked Example LINK**](https://surreynet.surrey.ac.uk/sites/default/files/2018-03/EXAMPLE_RISK_ASSESSMENT.pdf)

***How to complete your Risk Assessment (delete risk assessment guidance before submission)***

*As part of your ethics application you must assess any risks arising out of your proposed research. Your risk assessment should demonstrate that you have considered the risk of harm to yourself and others i.e. the research team, participants and anyone not directly involved for whom the research could have a negative impact.*

*\*Standard Operating Procedures*

*A standard operating procedure (SOP) is a set of step-by-step instructions to be followed routinely for the performance of designated operations or activities. You must demonstrate awareness of any SOPs and risk assessments relevant to your study and include their title, reference numbers and expiry dates.*

*SOPs will already exist for activities such as taking blood and MRI scanning. Consider writing SOPs for activities like take consent from vulnerable participants, so that everyone in your research team is working to the same standard.*

* ***Researcher***

*Consider whether any significant risks to the research team’s own health and wellbeing that could arise from the research project. These could be due to the nature of the project e.g. distress, tiredness etc. Or as a direct result of working with certain types of equipment e.g. risks from machinery, sharps or exposure to hazardous agents such as radiation, noise etc. Having identified these risks, suitable control measures need to be taken to effectively mitigate the risk to an acceptable level, in order that the work can proceed without detriment to either the researcher or the participants.*

* ***Lone working***

*Researchers may be working alone in situations that pose additional risks e.g. conducting interviews in a participant’s home. These risks need to be mitigated with additional measures taken to safeguard the researcher. Such measures may include; sharing your schedule of appointments and contact addresses with a colleague, carrying a mobile phone with programmed speed dial numbers, established call in procedures, escalation process in the event of a failure to call in at an agreed time etc.*

* ***Vulnerable groups***

*Research can often involve vulnerable groups, in which case the risk assessment would need to identify the protocols used to safeguard the researcher and the study group. Issues such as the consent process for vulnerable individuals, maintaining confidentiality of participants, the style of interview/ questioning being used, if enhanced DBS checks are required for the researcher etc. need to be considered as part of the risk assessment. The researcher would also need to demonstrate an understanding of safeguarding in terms of the protocols governing their conduct during the research project.*

* ***Participants Wellbeing***

*It is important to identify any risks that the research may pose to the participants’ physical or mental wellbeing. As part of our duty of care to participants, it is important to have adequate controls in place to address foreseeable risks arising as a direct result of participation in the research study.*

*It is important to have a procedure for dealing with possible disclosures or adverse events identified in your assessment. Detail procedures here or in the protocol.*

* ***Data Protection***

*The research process should provide adequate control over the integrity of the data gathered during the research project. There are however risks associated with the storage and use of research data that should be considered as part of the risk assessment process. Issues such as loss or theft of data held on a mobile storage device, corruption of data files, control of data transfer via open networks (the cloud), sharing data with research collaborators/ private businesses and data protection should all be considered as part of the overall assessment.*

* ***Adverse Publicity***

*It is important to highlight any potential risks or backlash the study may encounter once it’s advertised on public channels, especially via social media which can escalate out of your control. Consider whether any part of your study may be misinterpreted and how you would mitigate such a risk. Adverse publicity should be considered at both at the recruitment stage and also for any publishing.*

* ***Research Samples***

*Research is often supported by the taking and subsequent analysis of samples. These can range from physical samples of material through to biological samples taken from humans or animals. Samples that carry a risk of infection would require additional controls such as vaccinations and the use of Personal Protective Equipment (PPE) to be robustly implemented.*

*Legislative controls e.g. HTA (Human Tissue Act) are in place that tightly control the taking and use of biological samples. Further controls exist to restrict the transportation of materials e.g. transport of dangerous goods legislation (ADR). Import / Export control licence restrictions may also apply to some categories of material being brought into the UK. Failure to adhere to any of these controls would not only jeopardise the research project but may also result in the prosecution of the University.*

* ***Travel***

*Research may involve travel to locations where the risk to individuals is adjudged to be higher than that in the UK. Before you travel:*

* *Visit the University* [*Travel Insurance pages*](http://surreynet.surrey.ac.uk/staff-services/insurance/travel-insurance) *to complete Travel Cert to get a cover note and get general advice. It is the individual’s responsibility to ensure sufficient insurance cover is in place before departure.*
* *Visit the SurreyNet* [*Travel Health and Safety Advice pages*](https://surreynet.surrey.ac.uk/staff-services/business-travel/travel-health-and-safety-advice) *for advice and useful links.*
* *The* [*University Robens Centre Travel Health and Vaccination Clinic*](http://www.rcohs.com) *provides advice on the health risks associated with international travel as well as vaccinations and medication.*
* *If appropriate, use an external site such as the Foreign and Commonwealth Office* [*Foreign travel advice*](http://www.gov.uk/foreign-travel-advice) *or* [*Drum Cussac*](http://www.drum-cussac.net/self-registration) *for up-to-date travel security information. This information should be used to inform your assessment of the risk of travel to your proposed destination.*

*Whilst you are travelling:*

*The University uses a booking agent (Ian Allen) to arrange flights and accommodation for business travellers, as part of the Ian Allen service additional support is available should an emergency situation arise. The insurance company also provide a 24 hour helpline for emergencies – the contact details are on the cover note.*

### Data Management

*Aim: To describe how you will move, store or share any data in compliance with General Data Protection Regulations and University policy.*

*Other issues to consider if they are relevant to your research:*

* + - *If using a non-approved third party platform or if collecting identifiable special category data please contact* dataprotection@surrey.ac.uk
		- *Personal data used to distribute incentives should be kept separately from the research data, and deleted after the incentive has been distributed*
		- *Recordings – should be transferred from recording devices, saved to the UoS secure system and deleted after transcription*
		- *Data collected via a platform eg Qualtrics - data should be transferred from the platform to UoS secure system and then deleted from the platform as soon as possible*
		- *Sensitive data – should be transferred using Surrey DropOff* <https://dropoff.surrey.ac.uk/>
		- *If sharing data outside the UoS, please liaise with Research Contracts to see whether a data sharing agreement is required* <https://surreynet.surrey.ac.uk/research-contract-services>

### Ethical considerations

*Aim: to highlight any potential ethical considerations and how you will mitigate against them to protect your participant group. Possible issues: withdrawal criteria, dealing with sensitive situations, researcher safety, incentives.*

### Dissemination

*Aim: to highlight your dissemination policy and how you will ensure your research gets to the appropriate and widest audience possible.*

### References

*Aim: to cite appropriate references, putting your work into context, and demonstrating the breadth and depth of your research, and acknowledging other people’s work. You should reference whenever you use someone else’s idea.*

**Amendment History** *(to be completed for subsequent versions after initial authorisation)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Amendment No.** | **Protocol version no.** | **Date issued** | **Author(s) of changes** | **Details of changes made** |
|  |  |  |  |  |

List details of all protocol amendments here whenever a new version of the protocol is produced.