Project Title

*Try to use a descriptive, informative title that succinctly describes the study including the main research idea and the study type*

Short Title (if any)

*Sometimes referred to as a running title*

Study investigators

**Coordinating Principal Investigator**

|  |  |
| --- | --- |
| Title & name: |  |
| Institution: |  |
| Position: |  |
| Contact email and phone: |  |

**Study Contact Person**

|  |  |
| --- | --- |
| Title & name: |  |
| Institution: |  |
| Position: |  |
| Contact email and phone: |  |

**Co-Investigator**

|  |  |
| --- | --- |
| Title & name: |  |
| Institution: |  |
| Position: |  |
| Contact email and phone: |  |

*Add as many co-investigators as required*

Background and Rationale

*Provide an introduction to the study, including a brief review of the literature, the knowledge gap that the study is proposing to address and how the study will address this.*

Aims and Objectives

*State the aim/objectives of the research study, the key research questions and clearly defined hypotheses (where appropriate).*

 Methods

***Study Design***

*Qualitative methods (e.g. action research, focus groups, interviews, surveys), quantitative methods (e.g. case, cohort, cross-sectional, case-control, randomised controlled study)*

***Sample size and statistical power***

***Study Population (including eligibility/inclusion criteria)***

***Data sources/collection***

***Main study factors and outcomes***

*Provide information on the main study factors/exposure, any relevant covariates and outcome variables, and how they are defined.*

***Statistical analysis***

*Provide a description of the statistical methods that will be used including any qualitative methods, and quantitative methods (e.g. t-tests, chi-square tests, linear regression, linear models, generalized linear models).*

Ethical Considerations

*Consult the National Statement in Ethical Conduct in Human Research.*

*Determine the level of risk associated with the proposed activity (inconvenience, discomfort, harm).*

*If any risks are identified, indicate how they will be mitigated and/or addressed.*

*Provide information on how informed consent will be obtained or if a waiver of consent will be requested*

Data Governance

*Data collection: specify where data will be collected.*

*Data transfer & security (if applicable).*

*Data storage: indicate where and how the data will be stored.*

*Data access: specify how data will be accessed by investigators.*

*Data retention: specify the period of retention of the data following completion of the project.*

*Data disposal: specify how the information will be destroyed after the retention period.*

Outcomes and Significance

*Provide information on the potential benefits of the research, highlighting the potential significance of the findings (e.g. to inform future research, policy, planning and/or practice).*

*Provide information on the intended methods of dissemination of the study findings (e.g. internal report, presentation at unit/department/organisation level, publication in peer reviewed journal, presentation at scientific conferences).*

References