



HREA Project Description

Project Title

Acronym (if applicable)

Version (if applicable)

1. Principle Investigator
2. Associated Investigators
3. Research Involvement
 - 3.1 Protocol Governance
 - 3.2 Institution/Organisation Involvement
 - 3.3 Resources
 - 3.3.1 Funding
 - 3.3.2 Budget
4. Background (literature review, rationale/justification)
 - 4.1 Aims (expected outcomes)
 - 4.2 References
5. Project Description
 - 5.1 Research project setting (physical sites/online)
 - 5.2 Methodological approach (explain choice of method/explain choice of control arm)
 - 5.3 Participants (description/number/inclusion/exclusion criteria/sample size/statistical power)
 - 5.4 Participant Consent
 - 5.5 Participant Recruitment strategies and timeframes
 - 5.5.1 Timeframes
 - 5.5.2 Participant recruitment (overview if multiple participants)
 - 5.5.3 Participant recruitment specific to participants (if multiple types of participants)
 - 5.6 Approach/es to provision of information to participants and/or consent
 - 5.7 Project/Research Activities
 - 5.7.1 Workflow diagram
 - 5.7.2 Project activities
 - 5.8 Participant Commitment
 - 5.9 Project duration
 - 5.10 Participant follow up
6. Data Collection
 - 6.1 Data Collection/Gathering: What information are you going to collect/gather? (as required in addition to that outlined in the HREA)
 - 6.1.1 Data collected
 - 6.1.2 Data collection/gathering techniques
 - 6.1.3 Impact of participant withdrawal
 - 6.2 Data Management
 - 6.2.1 Type of data
 - 6.2.2 Accessing data
 - 6.2.3 Data governance
 - 6.2.4 Data provisioning
 - 6.2.5 Data security storage
 - 6.2.6 It security arrangements in place to protect the data collection

- 6.2.7 Data back-up
- 6.2.8 For what length of time will data be stored after completion of the study
- 6.2.9 Results and publications
- 6.2.10 Training of member of the project
- 7. Research (matching and sampling strategies/accounting for potential bias, confounding factors and missing information/statistical power calculation)
 - 7.1 Analysis
 - 7.2 Data linkage
 - 7.3 Outcome measures
- 8. Future (other potential use of data/project closure)