

RESEARCH PROJECT PROTOCOL

Project Title			
Lead Researcher	<i>Name</i> <i>Address</i> <i>Contact details</i>		
Sponsor <i>(if applicable)</i>	<insert>		
Funder <i>(if applicable)</i>	<insert>		
Relevant approval references <i>(if applicable)</i> E.g. IRAS number, Sponsor reference, REC reference	<insert> <insert> <insert>		
NIHR HDRC Coventry reference (to be allocated by HDRC)	<insert>		
Version number	<insert> <i>0.X for draft versions, final version should be 1.0</i>		
Date	<insert>		
Planned Start date	<Insert>		
Planned End date	<insert>		
Protocol Amendments <i>(if applicable)</i>			
Amendment Number	Protocol Version	Date of Amendment	Date of Approval

Confidentiality statement

All information contained within this document is regarded as, and must be kept, confidential. No part of this document may be disclosed to any Third Party without the written permission of the Chief Investigator and/or Sponsor.

PROJECT FLOW CHART *(if applicable)*

Figure 1: Flow of participants through the study

Key information to convey includes the timing of all study activity involving participants.

SCHEDULE OF EVENTS *(if applicable)*

Table 1: Schedule of Events **SAMPLE TO BE USED AS A GUIDE. AMEND AS APPLICABLE.**

Procedure	Screening	Baseline	Month1-2	Month3-4	End of research		
Eligibility assessment	X	X					
Informed consent		X					
Demographic data (DOB, sex, ethnicity, height and weight)		X					
Complete Questionnaire		X			X		
Interview				X			
Intervention			X				

Contents

PROJECT FLOW CHART (if applicable).....	2
SCHEDULE OF EVENTS (if applicable).....	3
LIST OF ABBREVIATIONS (if applicable).....	5
1. Background	5
2. Aims and Objectives.....	5
3. Research methods / techniques	5
4. Data Collection / Management.....	6
5. Dissemination of research findings.....	7
6. Public Involvement.....	7
7. References (if applicable).....	7

- *How participants / samples will be selected/involved*
 - *How participants will be approached and recruited*
 - *Where participants will be recruited from*
 - *Please explain your process for obtaining informed consent.*
 - *Where the research will take place*
 - *If you are conducting an observation, please explain what will be observed, what resources/equipment will be used to record observations (if appropriate) and who will be observing.*
 - *If you are conducting an interview, explain who will be conducting the interview, how and whether they will be recorded and how.*
 - *What steps you have taken to consider equality and diversity issues in your research plan*

4. Data Collection / Management

- *Include the following information where relevant -*
 - *What data will be collected? If data being collected consists of personal data or special category data (data such as a person's race, ethnic origin, political opinion, religious beliefs, trade union membership, physical or mental health condition or sexual life), please list below.*
 - *Will any personal data collected consist of digital images, video or audio recordings?*
 - *Has a privacy notice, participant information sheet and consent form been shared with all participants?*
 - *Who will be responsible for collecting and analysing the data?*
 - *Does the person retrieving the data have access to the data as part of their normal role or placement?*
 - *Who will be collecting the data on the researcher's behalf and how will this be checked for anonymisation?*
 - *How will the data be collected? (e.g. questionnaire, interview, focus group, case files)*
 - *What kind of data are you collecting? (Tick box – Anonymised, Pseudonymised, Identifiable)*
 - *What measures will be taken to ensure there is no breach of any duty of confidentiality of personal data collected as part of the research?*
 - *Who will have access to participant's personal data during the study? Please mention any access controls/restrictions.*

- *Where will the research data be stored and for how long?*
- *How will you ensure data is stored and destroyed securely?*
- *Will any data be shared with another organisation? If yes, is a Data Sharing Agreement in place and if so, has a copy been forwarded to Information Governance and added to the Data Sharing Register?*
- *Who will be the Data Controller?*
- *Is there a Data Processing Agreement or Data Sharing Agreement in place and if so, please state whether it has been checked by Information Governance. For external applicants, please consult with your organisation/institution's information governance team.*
- *Will any data be transferred out of the UK?*
- *Which country/countries will data be transferred to and what mechanisms are in place to ensure legal requirements are met?*
- *If you will be using personal identifiable data, how will you ensure that anonymity will be maintained when publishing results?*
- *Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.*

5. Dissemination of research findings

- *Describe the plans for disseminating the research findings.*
- *Explain details of acknowledgement and publication.*
- *Include information about how the results will be made available to participants, as well as professionals, and whether they will be notified of publication details*

6. Public Involvement

Describe how the public have been consulted about and/or involved in the development of this research and how will they be consulted about and/or involved throughout the project?

7. References (if applicable)

<Insert references>