The following schedule sets out the agreed allocation of study-related duties between the Sponsor (*add name as applicable* Royal Devon University Healthcare NHS Foundation Trust or University of Exeter), the Chief Investigator (CI) and the Clinical Trials Unit (CTU) (if applicable) for the (*add name*) study.

L= Lead responsibility X = Participating N/A= Not Applicable

Task	**Allocated to:**			**Comments**
	Sponsor ***Add Royal Devon/UoE***	**CI**	**CTU** ***Add Name or delete as applic. Further columns may be added***	
KEY DOCUMENT PREPARATION				
Protocol writing		*eg L*	*X*	
Protocol review				
Ensure protocol is compliant with HRA template and guidelines.				
Protocol amendment writing				
Protocol amendment review				
IRAS form and or College REC application, plus IRAS if it falls under 4b category (in project filter questions)				
Participant Information Sheet / Consent Form writing				
Participant Information Sheet / Consent Form review				
Case Report Form (CRF) design (paper or e-CRF)				
CRF review (including updates) and approval. (If eCRF validation of e-CRF)				
CRF printing				
Questionnaire(s) (validated or non-validated),and/or survey ,topic guides and/or interview questions				
Tests/scales/questionnaire(s)/checklists/diaries (e.g. Psychological batteries)				
Preparation of study-specific SOPs/work instructions				
Study-specific SOPs/work instructions review				

Preparation of instructional manual/script including amendments (e.g. intervention manual)				
Instructional manual/script review				
Preparation of other study-specific documents (e.g. recruitment materials, pocket cards etc.)				
Other study-specific documents review				
Registration of study on suitable register (pre application)				
FINANCE				
Negotiation of study budget (identification of activities)				
Cost attribution				
Maintain oversight of trial budget				
Provide financial reports to funder				
AGREEMENTS				
Ensure collaboration agreements are in place				
Selection, negotiation, management of vendors (e.g. professional transcription, translation, imaging, software licence(s), survey platforms)				
Ensure 3rd party agreements are in place (e.g. Data sharing agreements)				
Ensure insurance and indemnity arrangements are in place				
Ensure all Sponsor agreements are in place prior to commencement				
Provide and obtain sign off for Site Agreements (model or Organisation Information Document/OID) to participating sites, or Management Permission (Non-NHS) e.g. Care Homes				
APPROVALS				
Portfolio adoption application				
Preparation of initial Health Research Authority (HRA) & Research Ethics Committee (REC) application				
Review of initial HRA & REC application				
Submission of initial HRA & REC application				

Preparation of amendments (non-substantial and substantial)				
Review of amendments (non-substantial and substantial)				
Judge substantiality of amendments				
Submission of amendments to HRA, REC (as applicable)				
Ensure REC approvals (including amendments) are in place				
If applicable, ensure study is registered (e.g. ClinicalTrials.gov) before recruitment starts. Update registration as necessary				
Provide local document pack to sites and R&D offices				
Provide HRA approval & updated documents to sites				
Ensure CI has C&C (R&D) approval in place				
Confirm C&C (R&D) approvals and agreements are in place and issue 'green light' to allow recruitment to begin				
STUDY SUPPLIES MANAGEMENT				
Study supplies procurement including ancillaries (e.g. accelerometers, recording devices)				
Providing defined kit/supplies to sites and maintaining log/records				
Reordering stock				
SAFETY REPORTING (if required)				
Development of Adverse Event (AE) & Serious Adverse Event (SAE) reporting plan				
Provide Investigator training/information on safety reporting responsibilities				
Receipt SAE's from investigators and follow up as required				
Review SAE's for accuracy and completeness				
Maintain safety database/log				
Review all SAE's (Assess seriousness, causality and severity)				
Review all SAE's for relatedness				
Review all SAE's for expectedness				

Compile and send periodic reports of all reported SAEs to sponsor				
Reporting of adverse incidents that affect the health and safety of participants to REC				
MONITORING, COMPLIANCE AND QUALITY ASSURANCE				
Provide Trial Master File (TMF) template				
Compile and maintain TMF				
Perform and review risk assessment				
Generate and review Monitoring Plan				
Design of monitoring process and provide template materials / training to monitoring personnel				
Perform central data monitoring				
Generate data queries				
Resolve data queries				
Perform Investigator site monitoring visits as dictated by monitor plan and compile monitoring reports				
Maintain log of all Investigator site monitoring visits				
Maintain file of all monitoring reports				
Perform trial audits as required				
Maintain log of protocol / GCP non-compliance reports				
Record serious breaches				
Adjudge whether violations constitute serious breach				
Report serious breaches to REC as applicable				
STUDY OVERSIGHT (MEETINGS, REPORTS)				
Provide day to day management of trial				
Monitor on-going safety and ethics of trial				
Formalise & arrange Study Management Group (SMG)				
Prepare and circulate minutes of SMG				
Provide annual progress reports to Regulatory Authorities (REC) and Sponsor				
Provide annual reports to funder as required				

GENERAL STUDY MANAGEMENT AND TRAINING				
Study Site selection (distribution Expression of Interests/ EOIs, feasibility assessment)				
Provide study-specific training to staff				
Site Initiation				
Day-to-day correspondence with Investigators' research teams				
Specify content of TMF, Investigator Site File (ISF)				
Collate and maintain TMF				
Collate and provide ISF to sites (including your 'home' site)				
Maintain ISF				
Distribution of trial documentation to sites				
Newsletters				
DATA MANAGEMENT				
Build and test study database				
Database validation				
Maintain study database				
Develop Data Management Plan				
Review Data Management Plan				
Study data receipt from sites and query management				
Data locking prior to analysis				
STATISTICS				
Create and revise Statistical Analysis Plan (SAP) as required				
Approval of SAP				
Provide statistical analysis (including interim analysis, input for meetings, presentations & publications)				
END OF STUDY AND DISSEMINATION				
Send end of study notification to REC				

Close out visit and archive notification to sites				
Archive TMF, ISF and CRFs				
Develop Publication Plan				
Prepare study results for publication				
Prepare and submit study results reports to regulatory bodies in a timely fashion (e.g. REC)				
Post study results on registry if applicable in a timely fashion (e.g. ClinicalTrials.gov), Place results on Open Research Exeter, or other suitable repository				
Inform participants of results				
Secure destruction of relevant data on agreed destruction: E.g. Linking key, pseudonymised scales, questionnaires, batteries, consent forms, recordings (audio/visual).				

SIGNATURE PAGE

Signed by Sponsor Representative							
Name (Print)		**Position**		**Signature**		**Date**	

Signed by Chief Investigator							
Name (Print)		**Position**		**Signature**		**Date**	

Signed by CTU (*delete as applicable*)							
Name (Print)		**Position**		**Signature**		**Date**	