Schedule of Events Cost Attribution Template (SoECAT)
Study Information - template A

Version number 1.19 11 March 2020.
Please check the CRN website for the current version of this template.

Guidance
The guidance given on each tab should be read in association with the separate guidance document.

Please answer each question below (**NOTE: KEY FUNCTIONALITY NEEDED TO COMPLETE THE REST OF THIS TOOL IS NOT ACTIVATED UNTIL YOU HAVE PROVIDED AN ANSWER TO QUESTION 3**). Please only provide an IRAS reference number if you have already created an IRAS project for this study. All cells are free text other than questions 3, 5 and 11, which should be answered using the drop-downs, question 9, which auto populates from the dates given in answer to questions 7 and 8, and 10 which must be a whole number. Whilst we appreciate that it may be difficult to state with certainty answers to questions 7,8 and 10 best estimations should be provided to support the calculations within this tool. Questions 11, 12, 13 and 14 are for office use only.

1. IRAS Reference Number:	0
2. Short Study Title:	PhEAST
3. Are you making application for funding from a portfolio eligible Association of Medical Research Charities (AMRC) member?	No
4. Funder Name	NIHR-HTA
5. Number of Study Arms	2
6. Chief Investigator Name	Professor Philip Bath
7. Planned Start Date	01 October 2021
8. Planned End Date	30 September 2025
9. Duration (Months)	48
10. Projected Number of Sites	24

OFFICE USE ONLY	
11. Lead Local Clinical Research Network (LCRN) or Devolved Administration	East Midlands

12. Pre-application AcoRD Specialist Authorisation	Select yes for each that applies
This SoECAT has been completed for the named study-level application and the cost attribution is in line with the AcoRD guidance as of the given date	yes
SoECAT completion is not required because the study will not be included on the NIHR Clinical Research Network Portfolio, or equivalent in Scotland, Wales or Northern Ireland. The applicant has been advised that the study will not be eligible to have its NHS Support Costs or Excess Treatment Costs recompensed.	
SoECAT completion is not required because there are only Research Costs. The applicant has been advised that an IRAS schedule of events will need to be completed at IRAS Approval application stage, if the study is to take place in the NHS (including in HSC in Northern Ireland).	
The application is for a Programme Grant. The applicant has been advised that the SoECAT will need to be updated once trial protocols have been developed.	
Name of AcoRD Specialist	Harriet Savage
Date Authorised	13/06/2023
Additional clarifications from AcoRD Specialist	SoECAT updated to include Arm 3 - Cognition sub study to ask informant about capacity

13. Main Commissioner	
14. Post Award Triage Authorisation	
Name of Authoriser	

Standard of Care

Guidance
This tab should be completed to best reflect the standard of care that participants in the study would otherwise receive. Whilst it is acknowledged that standard care can vary within and between organisations and often be difficult to describe in a uniform fashion for a complex group of patients, providing a best estimation of standard of care allows key parties to assess the costs / cost savings associated with undertaking research.

If the proposed study does not involve any additional interventions to standard of care and also does not involve reducing the number or frequency of interventions (e.g. an observational study, a questionnaire study, etc.) this tab should be left blank.

Please note that this tab is intended only to form a baseline for costs, to allow excess costs/cost savings to be calculated. If your study includes a standard of care arm, you must populate one of the 'Per-Participant' Arm tabs with this standard of care.

For the sake of accuracy and efficiency you may copy and paste between tabs by selecting the relevant cells (columns A-AG only). If copying from the Standard of Care tab into one or more of the Per Participant tabs you must replace the 'x's with the AcoRD cost attribution using the drop down boxes. Where you are completing multiple Per Participant tabs with similar activities on each, you may also use the copy-paste function to provide a starting point before tailoring each tab appropriately.

Both the IRAS Reference Number and Per participant Standard of Care total cells autopopulate and should not be manually over-written.

IRAS Reference Number:	0
Per participant Standard of Care total	£ 33.00

Area of Activity (Select this first)	Specific Activity (Drop down only present when Area of Activity selected first – if required option is not available please follow guidance in Non-tariff Costs tab)	Duration (Minutes)	Undertaken by (drop down only)	Do not use	Day -x to -v	Day 0	Column2	Column3	Column4	Column5	Column6	Column7	Column8	Column9	Column10	Column11	Column12	Column13	Column14	Column15
		Complete only for procedures			Screen	Base	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14
Other Procedures or Activities	Medical history	15	Nursing/Manager		x															
Other Procedures or Activities	Concomitant medication check (at screening)	10	Nursing/Manager		x															
Interventions clinical	Weight & Height (including BMI if required)	20	Nursing/Manager		x															
Interventions clinical	Vital Signs measurements (Temp, BP, Pulse and respiration)	10	Nursing/Manager		x															

Standard of Care

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IRAS Reference Number:	0
Per participant Standard of Care total:	£ 33.00

Area of Activity (Select this first)	Specific Activity (Drop down only present when Area of Activity selected first – if required option is not available please follow guidance in Non-tariff	Duration (Minutes)	Undertaken by (drop down only)	Column16	Column17	Column18	Column19	Column20	Column21	Column22	Column23	Column24	Column25	Column26	Column27	Any additional columns must be added to the left of this column	Calculated Activity Cost	Total cost per Activity
		Complete only for procedures		Visit 15	Visit 16	Visit 17	Visit 18	Visit 19	Visit 20	Visit 21	Visit 22	Visit 23	Visit 24	Visit 25	Visit x			
Other Procedures or Activities	Medical history	15	Nursing/Manager														£ 9.00	£ 9.00
Other Procedures or Activities	Concomitant medication check (at screening)	10	Nursing/Manager														£ 6.00	£ 6.00
Interventions clinical	Weight & Height (including BMI if required)	20	Nursing/Manager														£ 12.00	£ 12.00
Interventions clinical	Vital Signs measurements (Temp, BP, Pulse and respiration)	10	Nursing/Manager														£ 6.00	£ 6.00
																	#N/A	#N/A

General Activities

Guidance
This tab should be completed with site level activities that are NOT undertaken on a per-patient basis (e.g. one-off set-up or close-down activities and similar). All activities should be given a cost attribution, in line with the DH AcoRD guidance. https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

The IRAS Reference Number cell autopopulates and should not be manually over-written.

IRAS Reference Number:	0

Area of Activity (Select this first)	Specific Activity (Drop down only present when Area of Activity selected first – if required option is not available please follow guidance in Non-tariff Costs tab)	Duration (Minutes)	Undertaken by (Required field - Drop down only)	Undertaken by (Optional field - free text)	Site Set Up	On Trial	Close site to recruitment	Site close out	Calculated Activity Cost	Research Cost (Part A)	Research Cost (Part B)	Research Cost	Service Support Cost	Treatment Cost
		Complete only for procedures												
Participant Identification	Eligibility check (exclusions)	15	Nursing/Manager	Research Nurse		Service Support Cost			£ 9.00	£ -	£ -	£ -	£ 9.00	£ -
Study Set Up	Site Initiation Visit	45	Nursing/Manager	Coordinator	Research Cost				£ 27.00	£ -	£ -	£ 27.00	£ -	£ -
Study Monitoring	Attend monitoring visit (Research Nurse)	20	Nursing/Manager	Coordinator		Research Cost			£ 12.00	£ -	£ -	£ 12.00	£ -	£ -
Study Close Down	Archiving (single box fee)		Admin/Data Entry	Administrator				Research Cost	£ 500.00	£ -	£ -	£ 500.00	£ -	£ -
Study Set Up	Site Initiation Visit	45	Medical Staff	PI	Research Cost				£ 66.15	£ -	£ -	£ 66.15	£ -	£ -
Study Set Up	Attendance at training	60	Nursing/Manager	Research nurse	Treatment Cost				£ 36.00	£ -	£ -	£ -	£ -	£ 36.00
Non Tariff Cost	Cost of company training/retraining on use of catheters and base station				Treatment Cost				£ -	£ -	£ -	£ -	£ -	£ -
Non Tariff Cost	Provision of PES catheters (560)				Treatment Cost				£ -	£ -	£ -	£ -	£ -	£ -
Non Tariff Cost	Provision of base stations (60)				Treatment Cost				£ -	£ -	£ -	£ -	£ -	£ -
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Per-Participant Activities (1)

This tab should be completed for ALL studies

Guidance

This tab should be completed for site-level, per participant activities. Where the study involves multiple arms, or the activities otherwise differ between groups of participants, one tab should be completed per arm. If your project has more than 5 arms, please contact hra.approvalprogramme@nhs.net for a bespoke template. All activities should be given a cost attribution, in line with the DH AcoRD guidance.
https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

The IRAS Reference Number cell autopopulates and should not be manually over-written.

The recruitment target for each arm should be manually entered into the Number of Participants cell.

IRAS Reference Number:	0
Study Arm Name, Phase or other Designator (optional):	Intervention arm
Number of Participants in Arm 1	250

Area of Activity (Select this first)	**Specific Activity** (Drop down only present when Area of Activity selected first - if required activity is not shown - follow guidance above)	**Duration** (Minutes)	**Undertaken by** (Required field - Drop down only)	**Undertaken by** (Optional field - free text)	Day -x to -y	Day 0	Column2	Column3	Column4	Column5	Column6	Column7	Column8	Column9	Column10	Column11
		Complete only for procedures			**Screen**	**Baseline**	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**	**Day 14**	**Day 90**	**Day 180**
Intervention																
Participant Consent Procedures	Informed consent	30	Medical Staff		**Service Support Cost**											
Other Procedures or Activities	Medical history	15	Nursing/Manager		**Treatment Cost**											
Other Procedures or Activities	Prescription for study	10	Nursing/Manager		**Research Cost**											
Other Procedures or Activities	Concomitant medication check (at screening)	10	Nursing/Manager		**Treatment Cost**											
Other Procedures or Activities	Randomisation (manual, IVRS or IWRS)	10	Nursing/Manager			**Research Cost**										
Other Procedures or Activities	CRF/eCRF completion including data transfer and query resolution	30	Nursing/Manager			**Research Cost**										
Other Procedures or Activities	Review/reporting of patient AEs/SAEs	15	Nursing/Manager			**Research Cost**	**Research Cost**	**Research Cost**	**Research Cost**	**Research Cost**	**Research Cost**	**Research Cost**	**Research Cost**	**Research Cost**	**Research Cost**	**Research Cost**
Non Tariff Cost	Telephone call	30	Nursing/Manager											**Research Cost**	**Research Cost**	**Research Cost**
Non Tariff Cost	PES catheter/stimulation	20	Nursing/Manager				**Treatment Cost**	**Treatment Cost**	**Treatment Cost**	**Treatment Cost**	**Treatment Cost**	**Treatment Cost**				
Interventions clinical	Weight & Height (including BMI if required)	20	Nursing/Manager		**Treatment Cost**											
Interventions clinical	Vital Signs measurements (Temp, BP, Pulse and respiration)	10	Nursing/Manager		**Treatment Cost**											
Interventions non clinical	Subject Questionnaire	10	Nursing/Manager			**Research Cost**								**Research Cost**	**Research Cost**	**Research Cost**

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Intervention		**Complete only for procedures**			**Screen**	**Baseline**	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**	**Day 14**	**Day 90**	**Day 180**

Per-Participant Activities (1)

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IRAS Reference Number:	0
Study Arm Name, Phase or other Designator (optional):	Intervention arm
Number of Participants in Arm 1	250

Area of Activity (Select this first)	**Specific Activity** (Drop down only present when Area of Activity selected first - if required activity is not shown - follow guidance above)	**Duration** (Minutes)	**Undertaken by** (Required field - Drop down only)	Column12	Column13	Column14	Column15	Column16	Column17	Column18	Column19	Column20	Column21	Column22	Column23	Column24
		Complete only for procedures		Day 365	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17	Visit 18	Visit 19	Visit 20	Visit 21	Visit 22	Visit 23
Intervention																
Participant Consent Procedures	Informed consent	30	Medical Staff													
Other Procedures or Activities	Medical history	15	Nursing/Manager													
Other Procedures or Activities	Prescription for study	10	Nursing/Manager													
Other Procedures or Activities	Concomitant medication check (at screening)	10	Nursing/Manager													
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Other Procedures or Activities	CRF/eCRF completion including data transfer and query resolution	30	Nursing/Manager													
Other Procedures or Activities	Review/reporting of patient AEs/SAEs	15	Nursing/Manager	**Research Cost**												
Non Tariff Cost	Telephone call	30	Nursing/Manager	**Research Cost**												
Non Tariff Cost	PES catheter/stimulation	20	Nursing/Manager													
Interventions clinical	Weight & Height (including BMI if required)	20	Nursing/Manager													
Interventions clinical	Vital Signs measurements (Temp, BP, Pulse and respiration)	10	Nursing/Manager													
Interventions non clinical	Subject Questionnaire	10	Nursing/Manager	**Research Cost**												

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Number of Participants in Arm 1	250

Area of Activity (Select this first)	**Specific Activity** (Drop down only present when Area of Activity selected first - if required activity is not shown - follow guidance above)	**Duration** (Minutes)	**Undertaken by** (Required field - Drop down only)	Column12	Column13	Column14	Column15	Column16	Column17	Column18	Column19	Column20	Column21	Column22	Column23	Column24
Intervention		**Complete only for procedures**		**Day 365**	**Visit 12**	**Visit 13**	**Visit 14**	**Visit 15**	**Visit 16**	**Visit 17**	**Visit 18**	**Visit 19**	**Visit 20**	**Visit 21**	**Visit 22**	**Visit 23**

Per-Participant Activities (1)

This tab should be completed for ALL studies

Guidance

This tab should be completed for site-level, per participant activities. Where the study involves multiple arms, or the activities otherwise differ between groups of participants, one tab should be completed per arm. If your project has more than 5 arms, please contact hra.appprovalprogramme@nhs.net for a bespoke template. All activities should be given a cost attribution, in line with the DH AcoRD guidance.
https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

The IRAS Reference Number cell autopopulates and should not be manually over-written.

The recruitment target for each arm should be manually entered into the Number of Participants cell.

IRAS Reference Number:	0
Study Arm Name, Phase or other Designator (optional):	Intervention arm
Number of Participants in Arm 1	250

Area of Activity (Select this first)	Specific Activity (Drop down only present when Area of Activity selected first - if required activity is not shown - follow guidance above)	Duration (Minutes)	Undertaken by (Required field - Drop down only)	Column25	Column26	Column27	Any additional columns must be added to the left of this column.	Calculated Activity Cost	Research Cost (Part A)	Research Cost (Part B)	Research Cost	Service Support Cost	Treatment Cost
Intervention		Complete only for procedures		Visit 24	Visit 25	Visit x							
Participant Consent Procedures	Informed consent	30	Medical Staff					£ 44.10	£ -	£ -	£ -	£ 44.10	£ -
Other Procedures or Activities	Medical history	15	Nursing/Manager					£ 9.00	£ -	£ -	£ -	£ -	£ 9.00
Other Procedures or Activities	Prescription for study	10	Nursing/Manager					£ 6.00	£ -	£ -	£ 6.00	£ -	£ -
Other Procedures or Activities	Concomitant medication check (at screening)	10	Nursing/Manager					£ 6.00	£ -	£ -	£ -	£ -	£ 6.00
Other Procedures or Activities	Randomisation (manual, IVRS or IWRS)	10	Nursing/Manager					£ 6.00	£ -	£ -	£ 6.00	£ -	£ -
Other Procedures or Activities	CRF/eCRF completion including data transfer and query resolution	30	Nursing/Manager					£ 18.00	£ -	£ -	£ 18.00	£ -	£ -
Other Procedures or Activities	Review/reporting of patient AEs/SAEs	15	Nursing/Manager					£ 9.00	£ -	£ -	£ 108.00	£ -	£ -
Non Tariff Cost	Telephone call	30	Nursing/Manager					£ 18.00	£ -	£ -	£ 72.00	£ -	£ -
Non Tariff Cost	PES catheter/stimulation	20	Nursing/Manager					£ 12.00	£ -	£ -	£ -	£ -	£ 72.00
Interventions clinical	Weight & Height (including BMI if required)	20	Nursing/Manager					£ 12.00	£ -	£ -	£ -	£ -	£ 12.00
Interventions clinical	Vital Signs measurements (Temp, BP, Pulse and respiration)	10	Nursing/Manager					£ 6.00	£ -	£ -	£ -	£ -	£ 6.00
Interventions non clinical	Subject Questionnaire	10	Nursing/Manager					£ 6.00	£ -	£ -	£ 30.00	£ -	£ -
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								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
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								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A

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Intervention		**Complete only for procedures**		**Visit 24**	**Visit 25**	**Visit x**							
								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
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								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A