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

Version number 1.19 11 March 2020.
Please check the <u>CRN website</u> 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
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

		Select yes for each
12. Pre-application AcoRD Specialist Au	uthorisation	that applies
This SoECAT has been completed for the	ne 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 bec	ause the study will not be included on the NIHR Clinical	
Research Network Portfolio, or equivale	ent 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.		
been advised that an IRAS schedule of	ause there are only Research Costs. The applicant has events will need to be completed at IRAS Approval place in the NHS (including in HSC in Northern Ireland).	
The application is for a Programme Gra need to be updated once trial protocols	nt. The applicant has been advised that the SoECAT will have been developed.	
Name of AcoRD Specialist	Harriet Savage	
Date Authorised	13/06/2023	
Additional clarifications from AcoRD	SoECAT updated to include Arm 3 - Cognition sub study to	
Specialist	ask informant about capacity	
		•
13. Main Commissioner]
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14. Post Award Triage Authorisation]
Name of Authoriser		1
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General Activities

Creatives.

The lab should be completed with alle level activities that are NOT undertaken on a per-patient basis (e.g., one-off set-up or close-down activities and smiles). All activities should be plane a cost attribution, in the with the DH AcoRD guidance. https://www.gov.uk.igovernment/publications/guidance-co-introducts-do

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

IRAS Reference Number: 0

Area of Activity Specific Activity	Duration	Undertaken by	Undertaken by					Calculated Activity	Research Cost (Part A)	Research Cost (Part B)	Research Cost	Service Support Cost	Treatment Cost
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please follow guidance in Non	tariff Costs tab)												
				Site Set Up	On Trial	Close site to recruitment	Site close out						
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Participant Identification Eligibility check (exclusions)	procedures	Nursing/Manager	In		Service Support Cost			£ 9.00			1-	£ 9.00	T-
Study Set Up Site Initiation Visit	15	Nursing/Manager Nursing/Manager	Research Nurse	Research Cost	Service Support Cost			£ 9.00 £ 27.00	£ -	£ .	£ 27.00	£ 9.00	
Study Monitoring Attend monitoring visit (Research	h Nurse) 20	Nursing/Manager	Coordinator	Research Cost	Research Cost			£ 12.00	£ .	E .	£ 12.00	f .	£ -
Study Close Down Archiving (single box fee)	inedae)	Admin/Data Entry	Administrator		research cost		Research Cost	£ 500.00		£ .	£ 500.00	£ .	
Study Set Up Site Initiation Visit	45	Medical Staff	PI	Research Cost				£ 66.15		f .	£ 66.15		£ -
Study Set Up Attendance at training	60	Nursing/Manager	Research nurse	Treatment Cost				£ 36.00	£ -	£ .	£ .	£ .	£ 36.00
Cost of company training/retrain		88											
Non Tariff Cost catheters and base station		88		Treatment Cost				£ -	£ -	£ -	£ -	£ -	£ -
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Guidance
This lab should be completed for site-level, per participant activities. Where the study involves multiple arms, or the activities ofherwise 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 beginder lengthst. All activities should be given a cost attribution, in the with the DH AcoRD guidance.

Into all the project interpretable and project interpretable and

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.

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

Activity selected first - if required activity is not shown - following activities activ	Area of Activity (Select this first)	Specific Activity	Duration (Minutes)	Undertaken by (Required field - (Optional field - free text)												
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Guidance
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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 E (optional):	esignator 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)	(Optional field - free text)	Day -x to -y	Day 0	Column2	Column3	Column4	Column5	Column6	Column7	Column8	Column9	Column10	Column11
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Intervention		procedures														

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

IRAS Reference Number:	
Study Arm Name, Phase or other Designator	
(optional):	Intervention arm
Alumbar of Darticinants in Arm 1	251

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Intervention			Complete only for		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
Other Procedures or Activities	Intervention	Transaction of the contraction o	procedures														
Other Procedures or Activities	Other Procedures or Activities	Informed consent Medical history	30	Medical Staff													
Other Procedures or Activities	Other Procedures or Activities	Prescription for study	10	Nursing/Manager													
CRF#c/RF completion including data transfer and guery resolution. 30 Nursing Manager		Concomitant medication check (at screening)	10	Nursing/Manager													
Other Procedures or Activities Query resolution 30 Nursing Manager		Randomisation (manual, IVRS or IWRS) CRE/aCRE completion including data transfer and	10														
Series of the Control of Control	Other Procedures or Activities	query resolution	30	Nursing/Manager													
Control Cont	Other Procedures or Activities	Review/reporting of patient AEs/SAEs	15	Nursing/Manager	Research Cost												
Service Servic	Non Tariff Cost	PES catheter/etimulation	30	Nursing/Manager	Research Cost												
Marie	Interventions clinical	Weight & Height (including BMI if required)	20	Nursing/Manager													
Column		Vital Signs measurements (Temp, BP, Pulse and															
	Interventions clinical	respiration) Subject Ossetionneire	10	Nursing/Manager	Beeserah Cont												
	III TOTALIST TOTI CITITOS	Capital Quality Inter-	10	Trui Sirigi Marager	Research Cost												
		-															

Guidance
This lab 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 lab should be completed per arm. If your project has more than 5 arms, please contact tha approvalprogramme@inhs.net for a beginder. All activities should be given a cost all following. In it will the DH Activity guidance.

It is a large to the project that the project is a state of the project that the p

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:
Study Arm Name, Phase or other Designator (optional):
Number of Participants in Arm 1

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 quidance 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	Column24 Visit 23

Guidance
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Into all this prevent participations guidance—statishing—the costs of the efficient and social-care research.

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

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

Area of Activity (Select this first)	Specific Activity (Drop down only present when Area of	Duration (Minutes)	Undertaken by (Required field -				Any additional columns must be	Calculated Activity Cost	Research Cost (Part A)	Research Cost (Part B)	Research Cost	Service Support Cost	Treatment Cost
,	Activity selected first - if required activity is	(Drop down only)	Column25	Column26	Column27	added to the left of		. 9				
	not shown - follow guidance above)	Complete only for		Visit 24	Visit 25	Visit x	this column.						
Intervention Participant Consent Procedures	Informed consent	procedures 30	Medical Staff						_		1-		
Other Procedures or Activities	Informed consent Medical history	30 15	Nursing/Manager					£ 44.10 £ 9.00		£ -	£ -	£ -	£ 9.00
Other Procedures or Activities	Prescription for study	10	Nursing/Manager					£ 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) CRF/eCRF completion including data transfer and	10	Nursing/Manager					£ 6.00	£ -	£ -	£ 6.00	£ -	£ -
Other Procedures or Activities	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 Interventions clinical	PES catheter/stimulation	20 20	Nursing/Manager				-	£ 12.00 F 12.00	£ -	£ -	£ -		£ 72.00 £ 12.00
interventions critical	Weight & Height (including BMI if required) Vital Signs measurements (Temp, BP, Pulse and	20	Nursing/Manager				-	£ 12.00	Ł .		L -	L .	£ 12.00
Interventions clinical	respiration)	10	Nursing/Manager					£ 6.00	£ -	£ -	£ -	£ -	£ 6.00
Interventions non clinical	Subject Questionnaire	10	Nursing/Manager					£ 6.00	£ -	£ -	£ 30.00	£ -	£ -
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IRAS Reference Number:	C C
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	Duration (Minutes)	Undertaken by (Required field -				columns must be	Cost	Research Cost (Part A)	Research Cost (Part B)	Research Cost	Service Support Cost	Treatment Cost
	Activity selected first - if required activity is not shown - follow guidance above)		Drop down only)	Column25	Column26	Column27	added to the left of this column.						
Complete only for				Visit 24	Visit 25	Visit x							
Intervention		procedures											
								#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
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